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Screening older people for impaired vision

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Abstract

A systematic review of trials about screening older people for visual impairment found no evidence that screening improved vision. We undertook a new trial nested within a larger cluster randomised trial of multidimensional screening for people aged 75 years and over. 106 general practices were randomised to: targeted screening in which only a small proportion of participants with a range of health problems were offered visual acuity screening, and universal screening in which all participants were offered visual acuity screening. People identified with impaired vision were referred to the eye services. Around 220 participants were randomly sampled from ten practices in each group and visual outcomes measured at three to five years.

The response rate to the baseline assessments was 76.1%. Over one third of eligible participants died before having an outcome assessment. Of those alive, 67.8% in the targeted screening group and 57.9% in the universal group completed an outcome assessment. At outcome 37.0% (307/829) in the universal group had visual acuity of less than 6/18 in either eye compared with 34.7% (339/978) in the targeted group (odds ratio 1.11, 95% confidence interval 0.76 to 1.62, $P=0.58$). The 25 item National Eye Institute Visual Function Questionnaire composite score was 86.03 in the universal group and 85.62 in the targeted group (difference 0.41, 95% confidence interval -1.68 to 2.50, $P=0.69$). Although visual impairment was common, few people benefited from subsequent intervention. Possible explanations for the lack of effect include: chance; under-detection of uncorrected refractive error and that only around half the recommendations for referral to an ophthalmologist resulted in referral.

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CHAPTER 1. BACKGROUND

1.1 Introduction

Visual impairment and older people

The Vision 2020 initiative recently launched by the World Health Organisation highlighted the need to identify effective strategies to improve vision among older people.¹ The importance of ageing populations has been recognised for many years. However because of patterns of declining mortality, official forecasts have severely under estimated the likely proportions of people aged over 65 years in developed countries.²

The introduction of the sight test fee in 1990 increased concern about untreated visual problems in older people in the United Kingdom,³ and a report from the Royal National Institute for the Blind renewed concern about sight loss in older people.⁴ The Department of Health has called for deterioration in sight among older people to be given 'particular attention'.⁵ There have been repeated calls for screening for visual impairment to be undertaken in primary care.⁶⁻⁹

Multidimensional assessment of older people

In practice screening for visual impairment is only likely to be one part of a broader screening package (multidimensional screening assessment). Multidimensional assessment of older people was originally developed in response to studies suggesting high levels of undetected medical or social problems among older people.^{10;11} Multidimensional assessment aims to determine an older person's medical, social, psychological and functional problems and to form a plan for treatment and follow-up.¹² While multidimensional assessment has been shown to produce some small overall benefits,¹³⁻¹⁶ exactly which procedures within the assessment are effective and which ineffective is uncertain.¹⁷ Most forms of assessment include some attempt to assess vision. Screening older people for visual impairment using a Snellen chart is recommended for inclusion in the Canadian Periodic Health Examination.¹⁸

Over the past decade there has been increasing recognition of the need to base preventive health interventions on sound evidence.^{19;20} Referring to health promotion interventions, the 1997 MRC Topic Review of Primary Health Care stated that:

"Appropriate research is needed to discriminate between current ineffective approaches that should be stopped, and effective programmes which should be introduced and maintained".²¹

The current situation in the United Kingdom

Since 1990 in the United Kingdom the primary care team have been required to offer an annual screening assessment to all patients aged 75 and over,²² specifically including an assessment of vision. There has been concern that the over 75 programme was introduced without adequate evaluation,²³ and one survey found that 68% of general practitioners thought the assessments unnecessary.²⁴ At the time this work commenced the over 75 programme was under review.²⁵

The method for assessing vision, threshold for action and the purpose of the visual assessment in the over 75 check were not specified in the GP contract,²² but the Royal College of General Practitioners recommended a simple question about visual function to identify unreported problems.²⁶

Vision is specifically listed as a domain to be included in the Single Assessment Process to be offered to all older people proposed in the National Service Framework for Older People.²⁷ In the most recently issued guidance about the Single Assessment Process,²⁸ the Department of Health states that *"the following scales - or elements from them - may be used to explore the domains and sub-domains of the single assessment process,"* and includes the following two questions about vision from the Lambeth Disability Screening Questionnaire.²⁹

Do you have difficulty ...

... seeing newsprint even with glasses?

... recognising people across the road even with glasses?

1.2 Review of non-trial literature around screening older people for impaired vision

Criteria used for the review

Specific criteria for reviewing the evidence around community screening programme have been proposed³⁰ (table1.1). The criteria are an adaptation of those proposed by Wilson and Junger³¹ and have been used in other published reviews of community screening programmes.^{32;33}

a. Does the burden of suffering warrant screening?
b. Is there a good screening test?
c. Are efficacious treatments or preventative measures available?
d. Will those at risk attend for or accept screening?
e. Why is there under-reporting and do people accept interventions
f. Can the health system cope with the programme?

Table 1.1 Suggested criteria for assessing the effectiveness of screening programmes

Results

(a) Does the burden of suffering warrant screening?

The prevalence of unreported visual problems among older people

The best estimates of prevalence of relevance to mass screening come from community based surveys in unselected populations. Different assessment techniques, definitions and criteria for visual problems have been used, but some consistent trends have emerged.

A recent survey found binocular visual acuity of less than 6/12 (below the UK driving requirements³⁴) in around 30% of people aged 65 and over.³⁵ Only 12% of older people with a cataract causing impaired vision were in touch with eye care services and only one third of those with substantial uncorrected refractive error had seen an optician in the past 12 months.³⁵

Similar results have been found in other surveys undertaken in the United Kingdom.³⁶⁻³⁸ In one of these less than half the older people with impaired vision were known to by their GP to have an eye problem and less than half had ever been in contact with the eye services.³⁷

Other prevalence surveys have used different methods of sampling (such as whether people living in institutions were included), diagnostic criteria, and methods of correcting refractive error producing contributing to differences in the results obtained. When these differences are taken into account, estimates for the prevalence of visual impairment among older people in other developed countries have been broadly similar, although on the whole slightly lower than estimates from United Kingdom populations.³⁹⁻⁴⁴

Cataract, age related macular degeneration and uncorrected or inadequately corrected refraction defects are the commonest disorders. While glaucoma is a much less common cause of visual impairment, it is an important cause of blindness.⁴⁵

Adverse effects of visual problems

A variety of adverse factors have been reported as associated with visual impairment. Functional status and quality of life are lower;⁴⁶⁻⁵⁰ social contacts are lower;^{42;47;51;52} and visual impairment is strongly associated with depression,^{51;53} falls,⁵⁴⁻⁵⁶ and hip fractures.⁵⁷⁻⁶⁰

(b) Is there a good screening test?

In a primary care setting a screening test needs to be quick, cheap, available, and able to be carried out easily by different members of the primary health care team who often play a leading role in screening older people.^{57;61} The assessment of visual screening tests is hampered by the lack of a gold standard, i.e. something that 'truly' measures vision and the impact of visual loss on a person's life.

Distance acuity

Snellen charts for testing acuity are available in 95% of general practices.⁶² However, inadequate attention to testing distance and illumination are common,⁶³ and poor lighting is a particular problem in patients' homes.⁶⁴ Design problems in the Snellen chart are the alteration in the number of letters on each line, and the irregular progression of the size of the letters as one moves up or down the chart.⁶⁵ Newer charts with equal numbers of letters on each line and which measure the minimal angle of resolution on a logarithmic scale (logMAR) are available.^{66;67} The repeatability of acuity measurements is higher with these newer charts than the Snellen chart.⁶⁸⁻⁷⁰

In patients with reduced visual acuity, the pinhole test usefully differentiates refractive visual failure from non-refractive.⁷¹ However, although pinhole correction fairly reliably indicates that visual loss is due to refractive error, failure to correct acuity by using the pinhole does not exclude refractive error.⁷¹

Visual function

Reduced visual acuity may not accurately reflect "need" for measures to improve vision, and other factors have been shown to be independent risk factors for self-reported visual disability among older people.⁷²⁻⁷⁴ Visual field loss (for example due to glaucoma) is found in 10-15% of people aged over 80 years,^{43;75} and even with the retention of good central vision and therefore normal or near normal visual acuity, visual field loss is itself disabling.⁷⁵⁻⁷⁹ Reduced contrast sensitivity is also a strong predictor of difficulties with everyday tasks.^{52;80;81} The ability to read letters on a chart, particularly in a clinic setting with optimal lighting levels, may not provide a good measure of the impact of visual problems on a person's life nor equate with the person's perceived need for intervention. While vision related quality of life and visual acuity are correlated, this correlation is nowhere near complete.⁸²⁻⁸⁵ However, to date the visual function indices that have been shown to be valid⁸⁵ would be too long to be feasible

screening tools. The development of screening tools that are better able to measure the impact of vision on peoples' lives are needed.

Methods of measuring visual function are discussed in more detail in Chapter 3.

Questions about vision

Questions about visual problems have been compared to visual acuity measurements in a number of studies⁸⁶⁻⁸⁹ (table 1.2). These show that single questions are generally poor at detecting clinically significant reductions in acuity.

Study	Question	Participants	Visual acuity comparison	Sensitivity	Specificity
Stone ⁸⁷ (UK)	'Do you have difficulty seeing distant objects (with spectacles if you have them)?'	Participants aged 40-64 who attended a multidimensional screening assessment	Binocular <6/18	28.4%	92.9%
Cullinan ⁸⁶ (UK)	'Are you able to recognise a friend across the road?'	Participants aged 18 and over who had already identified themselves as having some kind of visual problem	Binocular<6/18	64%	48%
Hiller ⁸⁸ (USA)	Two questions: 'Have you ever worn glasses or contact lenses?' and 'Do you have trouble with your vision even when wearing glasses or contact lenses?'	Participants in the National Health and Nutrition Survey aged 65-74.	Binocular less than or equal to 20/50 (Equivalent to between 6/12 to 6/18)	34.3%	84.1%
Smeeth ⁸⁹ (UK)	"Do you have difficulty seeing newsprint, even if you are wearing glasses"	Participants in a randomised trial of multidimensional screening assessment for people aged 75 years and over	Binocular presenting acuity <6/18	36.4%	94.3%

Table 1.2 Sensitivity and specificity of questions about vision in detecting reduced acuity

The rather different figures found in the study by Cullinan⁸⁶ may reflect the fact that all people in the study had previously identified themselves as having some kind of visual problem. Sensitivity in detecting an acuity less than 6/12 can be improved to 86% by combining scores from three questions,⁹⁰ (compared to 28-64% for one question), but clearly asking three questions takes considerably longer than a single question.

While one or two questions about self-reported visual difficulties are poor predictors of low visual acuity, the extent to which they can identify impaired visual function is not known.

Action threshold

There are no agreed criteria for the level of visual acuity which warrants intervention. Many of the adverse associations of reduced visual acuity outlined above are found to some degree at a visual acuity less than 6/12. The United Kingdom driving requirements correspond to an acuity of around 6/10.³⁴ The majority of patients undergoing cataract surgery achieve a visual acuity of 6/12 or better,^{91;92} and this level is also achievable for most patients with refractive errors.³⁶ Although the World Health Organisation defines low vision as binocular visual acuity less than 6/18 following correction of refractive error,⁹³ the American criteria for visual impairment is a best corrected acuity of less than 6/12.

Recent work has shown that the levels of vision at which people have difficulties with everyday tasks depend on the task, indicating the limitations of trying to define a level of vision as disabling.^{81;83}

Although somewhat arbitrary (being dependent on the context of the health system), a pragmatic action threshold can be set by considering the level of vision below which a person is likely to be offered interventions to improve their vision.

(c) Are efficacious treatments or preventative measures available?

It has been estimated that over 70% of the visual impairment (defined as binocular visual acuity less than 6/12) present in people aged 65 and over is potentially remediable.³⁵ However, in older age groups, among whom macular degeneration is relatively more common, the proportion of people whose vision can be improved is likely to be considerably lower than this. In addition, using a lower cut-off to define visual impairment (such as visual acuity less than 6/18), visual problems are more likely to be due to serious eye disease such as macular degeneration or glaucoma and less likely to be due to refractive error. Therefore for more severe visual loss, the proportion of people whose vision can be improved with treatment is again likely to be lower than the 70% estimate.

Acuity can be improved for most patients with refractive defects. Surgical treatment for cataracts is effective.^{92;94} Although visual loss due to glaucoma is usually irreversible, the identification and treatment of people with glaucoma can slow visual loss.⁹⁵ Similarly, treatment can slow visual loss for people with diabetic retinopathy.⁹⁶ A minority of people with age related macular degeneration may benefit from photocoagulation⁹⁷ or photodynamic therapy.⁹⁸ For the remainder, attention to lighting⁹⁹ and rehabilitation measures,¹⁰⁰⁻¹⁰³ can improve function and help lessen the disabling effects of the visual impairment. However, the evidence base for the effectiveness of visual rehabilitation to date is weak, limited to several small trials that mostly report different outcomes.¹⁰⁴ Larger high quality trials are underway.¹⁰⁴ Registration as blind, and to a lesser extent as partially sighted mobilises social support and makes people eligible for increased social security benefits.¹⁰⁵

(d) Will those at risk attend for or accept screening?

The proportion of older patients who receive regular assessments as part of the over 75 programme is difficult to assess because there is no obligation on practices to collect this data. In surveys, rates of 55%,¹⁰⁶ 63%,²⁴ and 48%¹⁰⁷ have been found, but practices, which responded to the survey

questions, are likely to represent the best performing practices. Ninety percent of people in the over 75 age group see their general practitioner at least once a year,¹⁰⁸ making high coverage rates feasible. Very high uptake rates have been achieved in the European based trials of screening older people¹² and in general practice based eye surveys.^{35;37} Although these rates may reflect the extra resources available in a research setting, they do show that high rates are possible.

(e) Why is there under-reporting and do people accept interventions and advice?

Factors influencing use of eye services

Work to date suggests there may be a variety of complex factors that influence older people's use of eye services.

The likelihood of having been in contact with an eye care provider has been shown to be higher among people with more education, higher income, and known eye disease or self-reported visual difficulty.^{109;110} While older age has been shown to increase the likelihood of someone being in contact with eye services, older people are also more likely to have under corrected refractive error.^{111;112} In the United States, African Americans have been found to be less likely than white Americans to use eye services^{109;113} and more likely to have visual impairment amenable that would benefit from interventions.¹¹⁴ However in the Women's Health Study, black women were more likely and Asian/Pacific Islanders less likely than white women to have had a recent eye examination.¹¹⁰

One study in the United Kingdom used focus groups of older visually impaired people to explore their experiences and needs.⁴⁶ This study suggested that decreased patient expectation in old age, a belief that nothing can be done to help and worries about costs were possible factors in under reporting visual problems. A qualitative study assessing barriers to eye services among Asian people (with no particular focus on older people) in Ealing has recently been undertaken. Reports from this study are currently being prepared. Major themes that emerged were a perception by

those people not in contact with the eye services were that general practitioners were uninterested in eye problems, and, for those people who were already in touch with the eye services language difficulties were a major problem (I Murdoch, personal communication).

A study has been undertaken to investigate the uptake of rural outreach eye care services in South India.¹¹⁵ This study found that service attendance amongst adults identified with an eye problem was very low (7%). People who attended were more likely to be male and live close to the service facility. People who did not attend had a range of reasons for not doing so including fear of their eyes being damaged by treatment, cost, ageism, fatalism and an attitude of being able to cope.

A number of studies have briefly considered the issues of why older people do not report visual problems or what influences their uptake of eye services as a small part of broader studies. Fear of costs has been cited consistently by older people in studies looking at reasons for non-attendance at opticians.^{4;46;111;116} Although free sight tests for older people were recently re-introduced, the cost of obtaining glasses was specifically detailed in all of these studies. Poor ability of older people to recognise their own visual loss was found in a screening project undertaken in hospital outpatients.¹¹⁷ In a community survey, the presence of other functional difficulties was associated with non-reporting of visual problems.⁸⁶ The author suggested that the non-visual difficulties dominated some peoples' perceptions of their problems. In the same survey some people raised the stigma of being labelled as blind as an explanation for not reporting their visual loss. Transport difficulties have also been suggested as barriers to attending eye services.^{118;119}

Patient preferences and patient concern have been found to be strong determinants of demand for cataract extractions in large scale surveys.^{120;121}

Uptake of interventions following screening

There are little data on whether older people attend referrals or accept interventions for previously unreported visual problems discovered by screening. In a general practice based survey one third of those referred to the eye services with a visual problem did not attend.³⁷ Estimates of attendance at referrals arising from multidimensional screening assessments have ranged from 46% to 76%.¹²² For assessments that specifically included a visual assessment, attendance rates of 70%,¹²³ 61%¹²⁴ and a range of 60-80% depending on the specific reason for the referral have been found,¹²⁵ although data specifically about vision related referrals are not available for any of these studies.

(f) Can the health system cope with the programme?

It could be argued that the United Kingdom health system is currently coping with visual screening as part of the over 75 programme. However, there are wide variations in the way the checks are performed.^{106;126} The coverage rate of the programme is not accurately known, and neither are the methods of testing vision, action thresholds and interventions offered by different primary health care teams. A recent questionnaire survey found that only around two thirds of practices responding offered a regular screening assessment to older people and that only half included a vision component. All practices that reported including vision used questions about visual difficulties to detect problems: none reported using acuity testing.¹²⁷ The additional effect on the health services of a national standard screening protocol with a high coverage rate achieved cannot therefore be assessed. Any increase in referrals to the eye services would clearly consume additional resources.

There has been a great deal of recent interest in the level of unmet need for cataract surgery in the United Kingdom and elsewhere.^{128;129} The Department of Health has recently announced a new initiative aimed at improving the level of and access to cataract services.¹³⁰

Summary

Unreported visual problems are common among older people and associated with a variety of adverse factors. A range of effective interventions exist and vision could be improved for a substantial proportion of people affected.

Possible screening tests exist, although to date there are no validated tools for screening visual function. High levels of population coverage for a screening programme are feasible within primary care. There is little good information available about whether older people found to have visual impairment at screening are likely to adhere to recommendations for investigation and treatment. Universal screening of older people for impaired vision and adequate management of all those people found to have a visual problem would have major consequences for the health service. Establishing the effectiveness of such a programme is therefore of great importance.

CHAPTER 2. SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS OF SCREENING OLDER PEOPLE FOR VISUAL IMPAIRMENT

2.1 Background

Most forms of multidimensional assessment for older people include some attempt to assess vision. Specific screening procedures for chronic open angle glaucoma or diabetic retinopathy have not been included in either trials or programmes of multidimensional screening assessments.

While the aims of multidimensional screening of older people are broad, any benefit arising from the inclusion of a vision component in the assessment will necessarily be dependent on improved vision or visual function. Therefore this review uses improvement in vision as the outcome measure of interest.

2.2 Objectives

To assess the effectiveness in improving vision of mass screening of older people for visual impairment.

2.3 Methods

Criteria for considering studies for this review

Types of studies

All randomised trials of visual or multidimensional screening in unselected people aged 65 or over in a community setting were included.

Types of participants

Participants were people aged 65 or over not identified as belonging to a particular risk group.

Types of intervention

Any attempt at population screening for visual impairment in a community setting, either vision screening alone, or as part of a multidimensional screening assessment, was included.

Types of outcome measures

The outcome included was the level of visual impairment in the population at the end of the trial. Assessment of vision by any method (questions about vision, measures of visual function or use of an acuity chart), at least six months after the initial vision screening assessment was included.

Search strategy for the identification of studies

1. Electronic searching

Trials were identified from the Cochrane Controlled Trials Register (CENTRAL), the Cochrane Eyes and Vision Group specialised register, MEDLINE and EMBASE.

MEDLINE was searched using the following exploded MeSH terms: 'mass screening', 'preventive health services', 'eye diseases', and 'diagnosis, eye', and the non-exploded MeSH terms: 'health promotion' and 'geriatric assessment'. Titles and abstracts were searched for the words 'geriatric' or 'elderly' combined with any of the following, using the Boolean operator "AND"; 'screening', 'assessment', 'health', 'function' or 'surveillance'. Other free text searches used the words 'macular degeneration', 'cataract' and 'presbyopia'. Wild card characters were used to ensure all forms of words are included. At all stages articles about animals and children were excluded. The results of this search were combined with the Cochrane Highly Sensitive Search Strategy phases one and two,¹³¹ see appendix 1.

Free text terms were used to identify possible trials in EMBASE, and the MeSH headings and free text terms were used to search CENTRAL.

Each of the studies selected was sought as a citation on the SciSearch database, and reports of articles that cited these trials were reviewed for relevance to the selection criteria.

2. Reference searching

Reference lists of both identified trial reports and of review articles were scanned for further relevant reports.

3. Personal communication

The named author for correspondence for each of the selected trials was contacted for information about any other trials.

4. Unpublished data

A vision screen may have been only one small part of a multidimensional screening programme, and data about vision outcomes may not have been included in published reports of trials. Therefore trial authors were contacted for further information about visual outcome data if this was not reported.

The inclusion criteria were applied in two stages. In the first stage, articles were included only if they were randomised controlled trials of either visual or multidimensional screening of unselected participants in a community setting which included patients aged 65 and over. Trials of screening undertaken on selected groups of patients were excluded on the grounds that the results would not answer the question under review. Studies including *only* adults aged under 65 were also excluded. The named author for correspondence for all trials identified in the first stage was contacted (at their current addresses verified by telephone), asking for any further unpublished data about visual screening tests used and visual outcomes. Non-responders were sent two reminders and were telephoned. The second stage inclusion criteria were then applied to all the trials included from the first stage: the availability of any visual outcome data, whether

formally tested or self-reported; and a follow up of at least six months to allow intervention for detected visual problems.

Selection of trials

The abstracts and titles of all identified citations were assessed, and full reports were obtained for studies which possibly fulfilled the selection criteria. Studies for which vision outcome data were available were selected for quality assessment and data extraction.

Assessment of methodological quality

Trial quality was assessed based on the recommendations in Section 6 of the Cochrane Reviewer's Handbook.¹³² Four parameters were considered. Each parameter of trial quality was graded: adequate (A), not clear (B), or inadequate (C). The criteria used were:

1. Concealment of allocation.

This was scored as Adequate (A) if there was some form of centralised randomisation scheme, an on-site computer system or sequentially numbered sealed opaque envelopes were used.

2. Attrition bias.

Graded Adequate (A) if follow-up rates were similar in the comparison groups.

3. Intention to treat analysis.

Graded Adequate (A) if performed.

4. Masking of outcome assessment.

Scored Adequate (A) if the outcome assessors were masked to the allocation. Because of the nature of the intervention, it would not have been possible to mask either recipients or providers of care to their allocation. Therefore, masking of recipients or providers were not used as quality parameters for this review, although information when available is presented.

For any trial graded B on any criteria (or C unless an explicit statement was made about the quality component in the trial report), the trial authors were contacted for clarification. There is strong empirical evidence that inadequate allocation concealment in randomised controlled trials leads to biased results.¹³³ For this reason trials scoring C on allocation concealment were excluded from the review.

Data extraction

Data about visual outcomes were extracted using paper data extraction sheets (appendix 2). The proportions of people with visual impairment in the experimental and control groups formed the comparison.

Sensitivity analyses

Three possible effect modifiers were identified prior to analysis. Firstly, trials of visual screening alone might be expected to produce a different effect to trials of visual screening included in a broader assessment. It was decided that these two sub-groups of trials would be analysed separately, because a pooled result would be difficult to interpret. Secondly, it is known that questions about vision, formal assessment using an acuity chart, and measures of visual function differ in their sensitivity and specificity for detecting reduced visual acuity, and use of different types of screening tools may lead to differences in the effects of screening.¹³⁴ Thirdly, differences in trial quality may produce differences in the effect size seen.

Sensitivity analyses to assess the effects of including or excluding trials which differed in these three characteristics were planned.

Data analysis

Analysis was undertaken using the *meta* commands¹³⁵ in Stata statistical software.¹³⁶ Heterogeneity among trial results was tested for using a standard chi-square test. Results of studies that were similar with respect to participants, interventions and outcome measures and for which there was no statistical evidence of heterogeneity of effect were combined to produce a summary relative risk using the fixed effects weighted variance method.

2.4 Results

Description of trials

2516 citations and abstracts were screened and 154 full text articles were reviewed in detail. Seventeen studies met the first stage inclusion criteria¹³⁷⁻¹⁵³ (randomised controlled trials of either visual or multidimensional screening of unselected participants in a community setting which included patients aged 65 and over). All 17 were trials of multidimensional screening. There were no trials which primarily assessed visual screening.

Requests for further information led to replies from authors of all 17 trials. Five trial met the final inclusion criteria i.e. visual outcome data with follow up of at least six months.^{139;145;149;150;152}

The five trials included a total of 3494 participants (table 2.1).

Response rates, visual screening methods and outcome measures are shown in table 2.2.

Reference	Participants and setting	Overall trial intervention	Follow up period	Allocation concealment*	Attrition bias*	Intention to treat analysis*
Vetter 1984 ¹³⁹ (UK)	People aged over 70 living at home registered with 2 general practices	Annual assessment at home by a health visitor (n=577) v usual care (n=571)	2 years	A	A	A
McEwan 1990 ¹⁴³ (UK)	People aged 75 and over registered with one general practice	Multidimensional nurse assessment at home (n=151) v usual care (n=145)	20 months	A	A	A
Vetter 1992 ¹⁴⁹ (UK)	People aged over 70 living at home registered with 1 general practice	Annual assessment at home by a health visitor, specifically aimed at reducing falls and fractures (n=350) v usual care (n=324)	4 years	A	A	A
van Rossum 1993 ¹⁵⁰ (Netherlands)	Respondents to a postal invitation to all people aged 75-84 living at home a defined geographical area	Four visits per year for three years by trained nurses (n=292) v usual care (n=288)	3 years	A	A	A
Wagner 1994 ¹⁵² (USA)	Health maintenance organisation enrollees aged 65 and over.	Multidimensional assessment by a nurse which included a visual assessment (n=635) v a general health promotion visit with no visual assessment (n=317) v usual care (n=607)	2 years	A	A	A

*Quality criteria graded as follows: A = adequate, B = unclear and C = inadequate (see text for more details).

Table 2.1 Randomised controlled trials of screening older people that include visual outcome data: participants, settings and interventions and trial quality

Reference	Response rate to screening	Visual screening method	Visual outcome measure
Vetter 1984 ¹³⁹ (UK)	96.0% (1286/1340) / ,	Two questions about glasses and difficulty seeing	Proportion with a positive response to the question 'Do you have any difficulty seeing (even when wearing your glasses)'
McEwan 1990 ¹⁴⁵ (UK)	88.4% (296/335)	Series of questions about vision and glasses	Proportion who 'always' or 'quite often' had difficulty reading ordinary newspaper (with glasses if worn)
Vetter 1992 ¹⁴⁹ (UK)	88.3% (674/698)	As Vetter 1984, with additional question about recent eye test	As Vetter 1984
van Rossum 1993 ¹⁵⁰ (Netherlands)	76.5% (1182/1545) (146 then excluded because ineligible for study. 580 then sampled from the remaining 1036, but sampling strategy unclear).	One question: "How do you assess your vision at present?" Possible answers: excellent, good, fair, not so good or bad	Proportion answering 'fair', not so good' or 'bad' to the screening question at the end of the study
Wagner 1994 ¹⁵² (USA)	35.2% (1559/4424)	Simple questions about visual function and use of glasses in a postal questionnaire	Proportion reporting visual problems on repeated mailed questionnaire at two years

Table 2.2 Response rates, visual screening methods and outcome measures

Setting and participants

Three of the studies were undertaken in the United Kingdom (McEwan 1990; Vetter 1984; Vetter 1992), all of which recruited participants from general practice (family practice). One study was undertaken in The Netherlands (Van Rossum 1993), and recruited from a defined geographic area. One study was undertaken in the United States (Wagner 1994), and recruited from a health maintenance organisation.

Response rates

Response rates to the invitation to have a screening assessment in the three United Kingdom based studies were all high (McEwan 1990; Vetter 1984; Vetter 1992). All three trials recruited participants from general practice. In the trial by van Rossum et al (1993), the initial response rate (people agreeing to take part in the study) was quite high at 76.5%. A sample was then drawn from all those eligible people who had agreed to participate, sampling 580 people from 1036. The method of sampling was unclear, but it was undertaken prior to randomisation. The response rate in the trial by Wagner et al (1994) was noticeably low. This was largely due to over 40% of the eligible participants not responding to the invitation to take part, and a further 13% actively refusing. Lower response rates in United States based trials compared with European based trials is a consistent feature of trials of multidimensional assessment of older people.¹² A response rate as low as 35% raises questions about the generalisability of the trial findings, because participants are likely to be a selective group.

Interventions

In all trials visual screening was undertaken as part of a broader assessment of health and functioning. In the trial by Wagner et al (1994), the assessments were undertaken at a clinic. In the remaining trials the assessments were undertaken in participants' homes. All five trials used questions about vision for the screening assessment. They did not measure vision. In the trials by Vetter et al (1984 and 1992), the questions about vision were part of a semi-structured interview. Assessments in all trials were undertaken by specially trained nurses or health visitors.

Outcome measures

All five trials used questions about vision to assess visual outcome. In Wagner 1994, visual outcome was assessed as part of a postal questionnaire. In the remaining trials the outcome assessment was by face to face interview.

Length of follow up ranged from two to four years.

Methodological quality

1. Concealment of allocation.

All five trials were graded adequate (A). Descriptions of the randomisation process were obtained for all five trials. Randomisation was undertaken centrally in all trials using random number tables or random number generators.

2. Attrition bias.

Because of the ages of the trial participants, there was a high mortality rate in most of the trials. However, loss to follow-up was low in all trials. Follow up rates were similar between the comparison groups in all the trials, and all five were graded adequate (A).

3. Intention to treat analysis.

All five trials were analysed by intention to treat, and were graded adequate (A).

4. Masking of outcome assessment.

The trial participants would clearly have been aware of whether they had received a screening assessment. Thus, in spite of attempts to mask the outcome assessors, which arm of the trial participants were in could have

emerged during the face to face outcome assessments. This phenomena was noted to a small degree in Vetter 1984 and Vetter 1992. Predicting that this phenomena was likely, such masking was considered impossible in McEwan 1990. In Van Rossum 1993, outcome assessors were masked as far as possible. Postal questionnaires to participants were used to assess outcomes in Wagner 1994.

Effects of screening

The results in all five trials were very similar (figure 2.1 and table 2.3). There was no evidence of heterogeneity of effect between the five trials ($Q=0.87$, degrees of freedom=4, $P=0.93$). The pooled risk ratio for self-reported visual problems at the time of outcome assessment comparing the intervention and control groups was 1.03 (95% confidence interval 0.92 to 1.16, $P=0.57$). The pooled odds ratio was 1.04 (95% confidence interval 0.89 to 1.22, $P=0.63$).

The trials were similar in all the aspects identified a priori as possible effect modifiers (visual assessment method used for screening, visual outcome used, whether visual screening was undertaken as part of a wider screening assessment, and trial quality). Therefore no sensitivity analyses were performed.

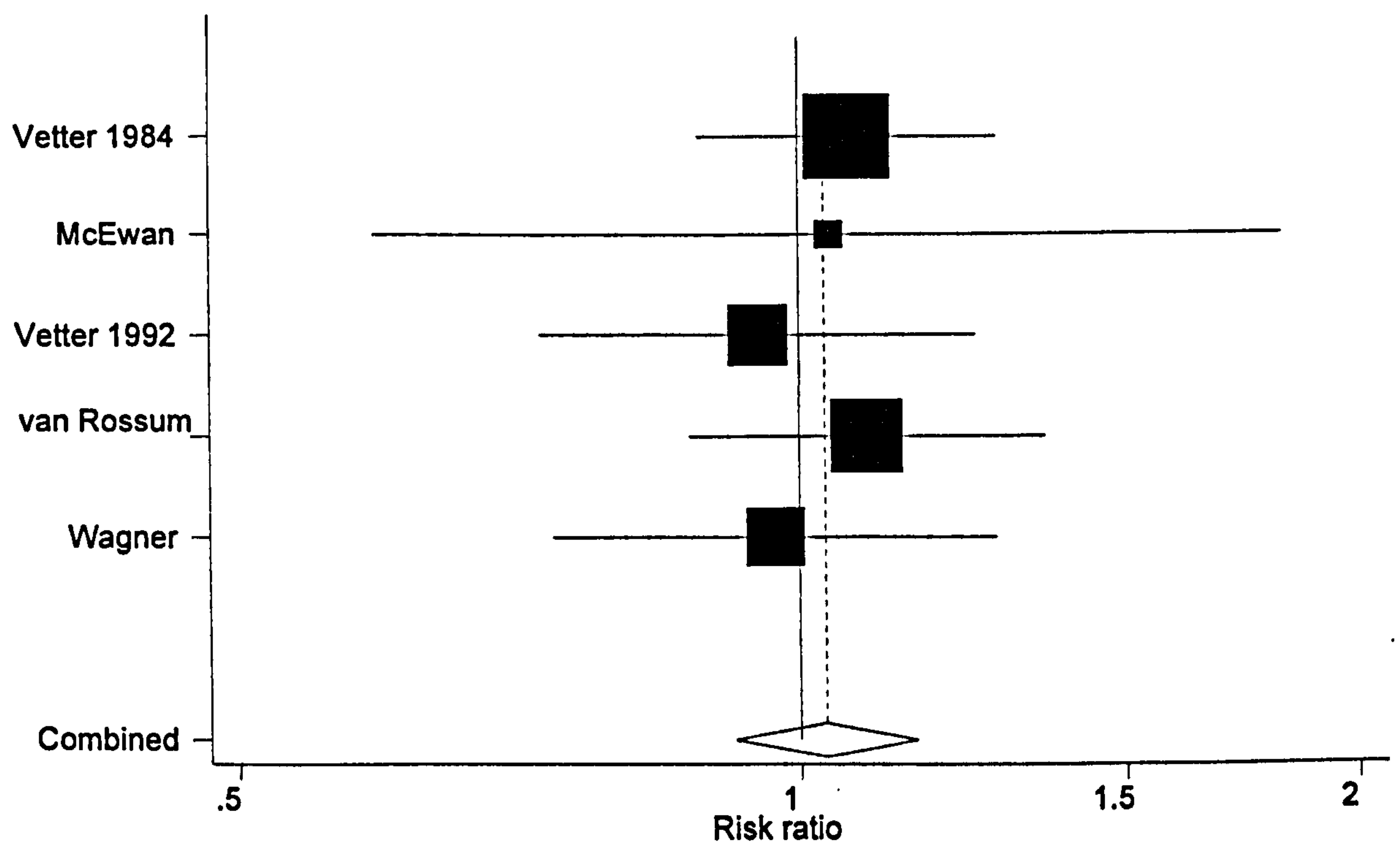


Figure 2.1 Relative risk of visual impairment at end of trial periods: individual studies and pooled estimate.

(The shaded squares and horizontal lines correspond to the studies' risk ratios and 95% confidence intervals. The area of the shaded squares reflects the weight each study contributes to the analysis, given by the reciprocal of the square of the standard error of the risk ratio. The diamond represents the combined relative risk with its 95% confidence interval. The solid vertical line corresponds to no effect. The dashed vertical line corresponds to the combined relative risk.)

Trial	Risk ratio (95% confidence interval)
Vetter 1984 ¹³⁹ (UK)	1.06 (0.88 to 1.28)
McEwan 1990 ¹⁴⁵ (UK)	1.04 (0.59 to 1.83)
Vetter 1992 ¹⁴⁹ (UK)	0.95 (0.73 to 1.25)
van Rossum 1993 ¹⁵⁰ (Netherlands)	1.09 (0.87 to 1.36)
Wagner 1994 ¹⁵² (USA)	0.97 (0.74 to 1.28)
Pooled estimate	1.03 (0.92 to 1.16) P=0.57 Test for heterogeneity: Q= 0.87, 4 df (p= 0.93)

Table 2.3 Relative risk of visual impairment at end of trial periods: individual study and pooled estimates

2.5 Discussion

The evidence from randomised controlled trials undertaken to date does not currently support the inclusion of questions about vision in regular multidimensional assessment programmes for unselected older people in a community setting. Although a reduction of 8% in the number of older people with visual impairment cannot be excluded, even this figure is disappointingly low. Visual impairment is common among older people, is frequently unreported, and is associated with a variety of adverse factors. Quick accurate screening tools exist and effective interventions exist for symptomatic patients. In light of this, the lack of improvement seen in these trials is somewhat surprising. It is of course possible that screening older people for visual impairment is an ineffective intervention. However, before coming to this firm conclusion, it is worth considering possible explanatory factors within the trials carried out to date.

A number of factors can be identified that may have contributed to the observed lack of effect on visual impairment. Firstly, a screening procedure alone would not be expected to lead to improvements in vision. Such improvements would be dependent on the subsequent interventions to improve vision. In four of the trials^{139;145;149;150} those reporting visual problems were given advice and referred to either an optician or to their general practitioner. In the other trial¹⁵² those reporting problems received information about resources in the community designed to assist those with poor vision. Information about whether participants attended these referrals, the diagnoses made, and interventions offered and accepted was not available. It is therefore possible that the management of those people found to have a visual problem was inadequate.

Secondly, the use of questions about vision both for the initial screening assessment and for the outcome assessment may have affected the results. Questions about vision have a low sensitivity and to a lesser extent a low specificity for detecting visual impairment when compared to formal acuity

testing. None of the trials used any kind of chart to measure vision either for the baseline screen or as an outcome measure.

A third possible factor is that visual function was not measured as an outcome in any of the trials. Visual function indices provide a measure of the impact of visual problems on a person's life. Interventions such as home lighting and visual rehabilitation may improve a person's vision related quality of life, but have no effect on distance visual acuity.¹⁵⁴ In recent years the value of visual function indices in assessing the effectiveness of interventions to improve vision has become widely accepted.^{48;155}

Finally, the visual assessment was only one component of the screening package in all five trials, and it is possible that visual screening performed in isolation may have produced a greater effect. This hypothesis was previously suggested as an explanation of the lack of effectiveness of screening for visual impairment seen in a trial of a multidimensional screening assessment among middle aged men.^{87;156} The general practitioners in this study felt swamped by the number of abnormal findings, and visual impairment was not usually considered a high priority.

This systematic review indicated the need for a large randomised trial of screening older people for visual impairment as part of a multidimensional screening assessment which overcomes the limitations of the trials to date. Specifically this trial should:

- have a clear plan of intervention for those people found to have visual impairment;
- use a formal assessment of visual acuity for the initial screening and outcome assessment;
- measure visual function as an additional outcome measure.

The proposal described below is for a trial that takes all these issues into account.

CHAPTER 3. SCREENING OLDER PEOPLE FOR IMPAIRED VISION: TRIAL DESIGN

3.1 Background

The MRC Trial of the Assessment and Management of Older People in the Community

Overview

The initial randomisation and the interventions being assessed in this study had already occurred as part of the MRC Trial of the Assessment and Management of Older People in the Community. This is a large randomised controlled trial taking place in 106 general practices recruited from the MRC General Practice Research Framework. Practices are representative of the United Kingdom population as assessed by deprivation (as measured by the Jarman score¹⁵⁷) and mortality rates (Standardised Mortality Rates). Appendix 3 gives more details of the study which is described in more detail elsewhere.^{89;158} In brief, the aim of the study is to determine the optimum methods of identifying disease and need in people aged 75 years and over within primary care (as required by the GP contract). The study encompasses a wide range of health problems among older people; that is, it is a multidimensional model of screening. Practices were randomised to several methods of assessment and management of older people. This trial will provide information on the overall effectiveness of different models of multidimensional screening. It also offers a unique opportunity specifically to determine the effectiveness of screening for visual impairment as part of a broader screening package. This trial will overcome the design problems identified with previous trials. Specifically this will be the first trial to use formal visual acuity testing and to have a clear plan of intervention for those people found to have visual problems.

Randomisation

In the MRC Trial of the Assessment and Management of Older People in the Community, practices were randomly allocated as follows:

(A) brief assessment by questionnaire followed by a detailed assessment, including visual acuity, only if indicated (the control group for this study) - *the targeted screening group*

(B) brief assessment by questionnaire followed by a detailed assessment including visual acuity for all patients (the intervention group for this study) - *the universal screening group*

Randomisation in the MRC Elderly Screening Trial was by practice. It was felt that individual randomisation would produce practical difficulties within the practices and may introduce bias (see discussion of cluster trials below). Randomisation by practice ensured that everyone in the same practice was offered the same model of screening, thus reducing the scope for contamination bias. A computer generated randomisation list, stratified by Jarman and SMR tertile, was drawn up by the statistician and practices were randomly allocated centrally at the London School of Hygiene and Tropical Medicine as they were recruited to the trial. Because of the nature of the intervention, it was not possible to blind participants or researchers to the group assignment. Randomisation was undertaken by computer, with stratification on the key factors (Jarman score and mortality rates) which may influence the outcome measures.

The basic design of the trial and visual assessments undertaken at baseline are shown in figure 3.1.

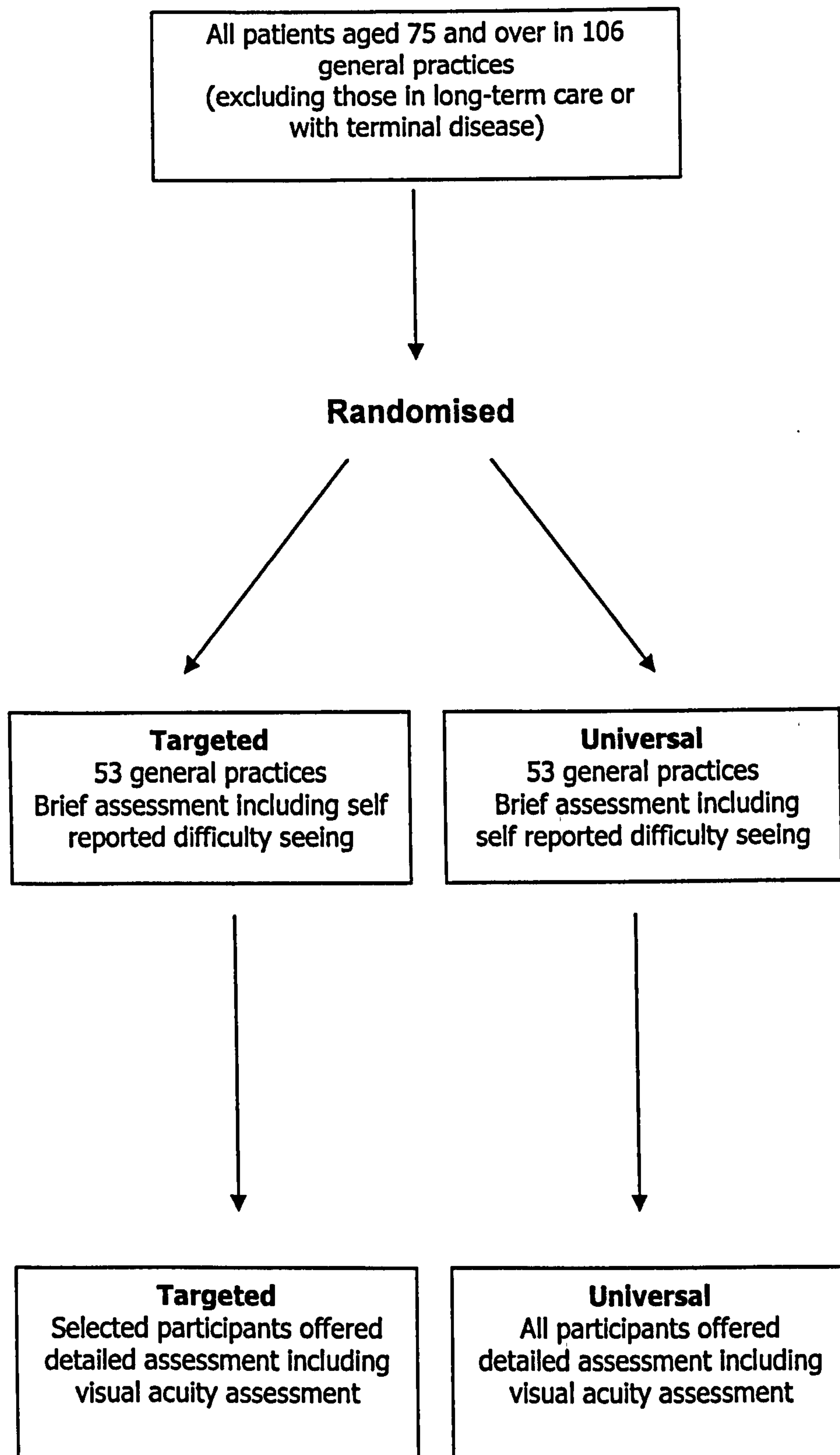


Figure 3.1 Design and vision screening at baseline in the MRC Trial of the Assessment and Management of Elderly People in the Community

The intervention

In the brief assessment, as one of the 35 questions about their health, participants were asked the following question on vision: "Do you have difficulty seeing newsprint, even if you are wearing glasses?". Possible answers were "No difficulty", "A little difficulty" and "A lot of difficulty". This question is one of the ten items in the Organisation for Economic Co-operation and Development long term disability minimum core set,¹⁵⁹ and was recommended as a brief screening tool by the Royal College of General Practitioners.²⁶

In the targeted screening arm, criteria for triggering to the detailed assessment were three or more problems identified from the brief assessment or any one of four "serious" symptoms (unexpected weight loss, frequent falls in previous month, vomiting blood, coughing blood). In the universal screening arm, all participants had a detailed assessment.

Visual acuity testing

During the detailed assessment, the participants' distance visual acuity was measured at 3 metres using a Glasgow Acuity Chart⁶⁷ This chart was developed by researchers at Glasgow Caledonian University and is designed according to the same principles as the Baillie-Lovie chart. It measures the minimal angle of resolution on a logarithmic scale (logMAR). The use of the logMAR chart is discussed in more detail below. All nurses taking part in the study were given a detailed training session on how to assess vision using the chart, and were specifically instructed that participants be encouraged to try and read as many letters on each line as possible. Vision was measured at one metre if there was no three metre space available (for example in some participants' homes) or people were unable to read any letters at three metres.

Referral criteria

The nurses were asked to refer as follows:

- (1) For anyone with a pinhole vision of less than 6/18 in either eye (logMAR

score 0.5 or more), referral to an ophthalmologist was recommended, unless:

- they had been seen by an ophthalmologist in the previous year;
- they were registered blind or partially sighted.

(2) Anyone with presenting vision of less than 6/18 that improved with pinhole to better than 6/18 was advised to visit an optician.

The referral criteria were an attempt to ensure that people referred were those likely to benefit from interventions (discussed in Chapter 9).

Baseline data collection occurred between 1995 and 1999. Prior to commencing the assessments, the nurses and lay interviewers attended a training session (with the exception of a few practices that joined the study late in which case the training took place at the practice). The nurses involved in the study were mostly existing practice nurses involved in practice based research: some of the nurses devoted all their time to research activity.

Ethical approval for all aspects of the study was obtained from relevant ethics committees.

We undertook a nested trial within the MRC trial, specifically to examine the effectiveness of the visual acuity screening component of the study.

Cluster randomised trials

Cluster randomised controlled trials are trials in which the unit of allocation consists of clusters (such as whole communities, organisations or geographical areas) rather than individuals.¹⁶⁰⁻¹⁶² A commonly used cluster unit is the primary care clinic (general practice).¹⁶³⁻¹⁷³

Reasons to randomise clusters

There are a number of reasons to randomise at the cluster rather than at the individual level, including:

- The intervention occurs at a cluster level, for example a practice wide smoking cessation intervention.¹⁷⁴
- It may be considered unethical or clinicians may feel uncomfortable about offering an intervention to some patients in a clinic while not offering the intervention to others, for example a new screening test.¹⁷⁵
- Risk of contamination between the allocation groups. Information, educational strategies or advice could easily be shared between individuals within a practice creating a clustering effect.¹⁷⁶ For example in a trial of safety advice at child health surveillance consultations, randomising families within the same practice could have led to some families in the control group being inadvertently exposed to elements of safety advice intervention.¹⁷¹ Randomising at the level of the general practice aims to avoid this contamination between the randomised groups.

All three of these reasons contributed to the decision to adopt a cluster design for the MRC Elderly Screening Trial and the nested trial of vision screening.

Statistical considerations

Individuals within the same cluster may be more similar than individuals selected from other practices i.e. observations may be correlated.¹⁷⁷ The intraclass correlation coefficient is a commonly used measure of the extent of the correlation between clusters.¹⁷⁸ Because correlated responses do not contain as much information as independent responses, within cluster correlation reduces the power of a trial and widens confidence intervals and increases P values of the results. Ignoring "intraclass correlation" will lead to studies that are too small to be useful and will underestimate the degree of random error in the effects observed. See description of analyses below.

Reporting of cluster randomised trials

Poor reporting of cluster trials is a recognised problem and attempts are being made to extend the CONSORT statement¹⁷⁹ to include cluster trials.¹⁸⁰ Reporting in this thesis follows these guidelines as much as possible.

3.2 Screening older people for impaired vision: a nested trial within the MRC Trial of Assessment and Management of Older People in the Community

Aims and objectives

To determine the effectiveness of mass screening for visual impairment in unselected older people (aged 75 or over) in a community setting as part of a multidimensional screening programme. A secondary aim is to assess barriers to treatment of visual impairment among older people.

Plan of investigation

Overview

The use of simple screening procedures (including a question about visual problems) with subsequent detailed assessment (including visual acuity testing) for those people found to have problems at the initial screen was recommended by the Royal College of General Practitioners in response to the introduction of the over 75 checks in 1990.²⁶ This was the intervention used in arm (A) which therefore represented current “usual practice” at the time of the study and formed an ideal control group. Baseline data from the MRC Elderly Screening Trial showed that on average less than 20% of the participants in group (A) had a formal test of visual acuity. Arm (B), in which all participants received a formal test of visual acuity, comprised the intervention group.

We measured visual acuity, visual function (self-reported disability) and collected data about use of eye services on a sample of participants from each arm of the MRC Elderly Screening Study.

Practice recruitment and selection

We planned to re-examine a minimum of 2000 participants from 20 practices within the main trial (see study power below). Ten practices were selected from each of the two arms (A) and (B) of the main trial. Full details of practice and participant recruitment and selection are given in Chapter 6.

Inclusion criteria

All people who were eligible for the baseline assessment in the MRC Trial of the Assessment and Management of Elderly People in the Community. This means all people who were aged 75 or over and registered with participating general practices at the time of the baseline assessments (1995 to 1998 depending the practice concerned).

Exclusion criteria

The only people who were specifically excluded from the outcome assessment were people who were: too ill to participate (defined as it being likely that the person would have found it unpleasant or impossible to complete an assessment); had died; or had moved away from the practice area. People who were in long-term care or had terminal disease at the time of the baseline assessments were excluded from the MRC Elderly Screening Trial and were therefore not included as part of the nested vision screening trial.

Outcome measures

Primary

There were two primary outcome measures.

Visual acuity

Impaired vision (defined as visual acuity less than 6/18) in one or both eyes.

In developed countries interventions (such as cataract extraction) are undertaken on the basis of reduced acuity in one eye, even if the acuity is good in the other eye. The justification for the choice of primary outcome measure is that it directly measures the intervention which was aimed at impaired vision in either (or both) eyes. The primary outcome measures will

answer the primary research question: “does testing vision during multidimensional health assessment for persons over 75 lead to a significant reduction in the prevalence of visual impairment in those screened when compared to those given only a brief assessment during which a single question on visual difficulty is asked?”

Visual function

The composite (overall) score from the National Eye Institute Visual Function Questionnaire (25 item version).

Secondary

Visual acuity

- Binocular presenting impaired vision (defined as a visual acuity less than 6/18). The binocular acuity measures functional "everyday" vision.
- Impaired vision (defined as visual acuity less than 6/18) in one or both eyes after pinhole correction. This is a measure of visual impairment that is unlikely to be due to refractive error.
- Visual acuity less than 6/12 in one or both eyes.
- Binocular presenting visual acuity of less than 6/12.

Visual acuity less than 6/18 represents a considerable level of impairment. An acuity between 6/12 and 6/18 can itself represent substantial loss of vision, and interventions such as cataract extraction would be undertaken (in developed countries) at a visual acuity between 6/12 and 6/18. A binocular acuity of less than 6/12 is well below the United Kingdom driving requirements. It is therefore of some interest to see the effect of screening on milder levels of visual loss.

In addition to the above binary outcomes, the mean logMAR acuity in the two groups will be compared as follows:

- binocular presenting vision;
- best eye acuity both with and without pinhole correction;
- worse eye acuity both with and without pinhole correction.

Visual function

Sub-scales of the National Eye Institute Visual Function Questionnaire (25 item version) which measure specific areas of visual function.

Barriers to improving vision in older people

We also aimed to assess possible barriers to improving vision in older people.

Notes on specific outcome measures

(a) Visual acuity

Visual acuity was measured at 3 metres with a Glasgow Acuity Chart.⁶⁷ This chart was developed by researchers at Glasgow Caledonian University. The chart overcomes specific problems with the Snellen chart discussed in Chapter 1: it has the same number of letters on each line, and there is regular progression of the size of the letters as one moves up or down the chart. The Glasgow Acuity Chart measures vision on the logMAR scale. The logMAR score is the log (base 10) of the minimal angle of resolution of the letters read for that score. This chart was chosen because:

- it applies modern scientific principles to the measurement of visual acuity;
- the regular progression in letter size moving up or down the chart allows the modelling of visual acuity data on a continuous scale;
- it is relatively cheap;
- it is portable meaning the research nurses could use the chart on home visits;
- it was used for the baseline detailed assessments thus providing a repeated measure for a sample of participants.

The chart is designed for use at 3 metres, or 1 metre for the measurement of very poor vision when people can see no letters correctly at 3 metres. The whole test can be performed at 1 metre if there are space restrictions.⁶⁷

The chart has previously been used in a large survey of visual acuity among older people in the United Kingdom.³⁸

Appendix 12 shows the relationship between Snellen visual acuity and logMAR scores.

(b) The pinhole test

Visual acuity measured through a pinhole (for each eye separately) provides an estimate of acuity corrected for any refractive error.⁷¹ In patients with reduced visual acuity, the pinhole test therefore usefully differentiates refractive visual failure from non-refractive. This facilitates a rational referral plan: to an optician for people with uncorrected or inadequately corrected refractive error, and to an ophthalmologist for people with reduced acuity not due to refractive error.

(c) Visual function

Visual acuity may not always correlate with visual functioning i.e. how well a person functions in everyday tasks which require vision.⁷²⁻⁷⁴ In recent years the value of visual function indices in assessing the effectiveness of interventions to improve vision has become widely accepted.^{48;85;155} A range of assessment tools have been developed to try and assess the impact of visual problems on level of functioning and quality of life.^{85;181-187} Scales that specifically assess visual problems are more sensitive to differences in vision related functional impairment better than generic health status scales.^{76;188;189}

Two of the most widely recognised scales are the VF-14¹⁸² and the National Eye Institute Visual Function Questionnaire.^{183;184}

The VF-14 was developed and validated earlier¹⁹⁰⁻¹⁹² and has been widely used,^{76;92;189;193-200} notably in the assessment of cataract outcomes

The NEI VFQ was developed in an attempt to overcome two perceived limitations in existing questionnaires:¹⁸⁴

- existing measures of visual function emphasised difficulty with tasks and symptoms rather than emphasising the influence of visual disability on other aspects of health related quality of life such as emotional well being or social function validation;
- the best validated measures (such as the VF-14) were designed for use among people with one specific eye disease: cataract in the case of the VF-14.

The NEI VFQ has been validated and used^{76;183;184;189;195;201} in a range of eye conditions and is now widely used for vision research in the United States. A shortened version consisting of 25 items (NEI VFQ-25) has recently been developed specifically for settings such as clinical trials where length of interview is a major consideration.^{202;203} The NEI VFQ-25 has been shown to be reliable and valid across a range of eye conditions^{202;203} and in different populations²⁰⁴ and has been used in a number of studies.²⁰⁵⁻²⁰⁷

Although the NEI VFQ appeared to be preferable as a visual function outcome measure, we could not identify any published reports of its use with older people in the United Kingdom. We therefore decided to pilot its use, specifically comparing it with the VF-14, a measure that has been successfully used to assess visual function in older people in the United Kingdom.¹⁹³

(d) Use of eye services

Information was collected from people found to have visual impairment at the screening assessments on whether they had attended any eye services they were referred to, and whether they adhered to interventions or advice offered. Possible reasons for not taking up available services were elicited. For all people who had ever seen an ophthalmologist or who were eligible for referral to an ophthalmologist following the baseline assessment the research nurses undertook a search of medical records for any letters relating to vision. A structured data extraction form was used for obtaining data from the participants GP records.

Study power and sample size

Power calculations for and analysis of controlled trials in which the unit of allocation is the individual assume that observations on individuals are independent. In a cluster trial this is not true: observations on individuals within the same cluster may be correlated.^{177;208;209} Because correlated responses do not contain as much information as independent responses, within cluster correlation affects the power of a trial and the precision of the estimates of effect. Failure to take this intraclass correlation into account when planning a trial will lead to underpowered studies that are too small to provide useful estimates of the effects of interventions.

The intraclass correlation coefficient

The extent to which within cluster correlation increases the sample size required for a study is known as the design effect or inflation factor. The design effect depends on the average cluster size (m) and the intraclass correlation coefficient (ρ), and is given by:²¹⁰

$$\text{design effect} = 1 + (m-1) \rho \quad [1]$$

The design effect is the ratio of the variance of an estimator under cluster sampling to its variance under individual random sampling:¹⁷⁸

$$\rho = \sigma_b^2 / (\sigma_b^2 + \sigma_w^2) \quad [2]$$

where σ_b^2 is the between cluster component of the variance and σ_w^2 is the within-cluster component of the variance.

If the design effect is 4, then a cluster trial will require 4 times the number of individuals required by a simple randomized trial of individuals. When $m=1$, we have a simple randomized controlled trial with a design effect of 1. Similarly if there is no within cluster correlation, the between cluster variance will be zero,

the intraclass correlation coefficient will be zero and again the design effect will be 1.

Statistical methods

To calculate the intraclass correlation coefficients, the methods presented by Donner and Klar were used.¹⁶² Formula 2 given above for ρ represents a hypothetical situation in which both clusters and individuals within clusters are drawn at random from a population. An estimate of ρ (ρ_1) can be obtained by performing a one way analysis of variance (ANOVA).²¹¹ This method is valid for both binary and continuous outcomes.^{211;212}

$$\rho_1 = (MS_b - MS_w) / (MS_b + (m - 1) MS_w) \quad [3]$$

where MS_b and MS_w are the mean squares from the ANOVA table for between and within clusters and again m is the average size of the cluster.

Because the size of each cluster varied, we substituted m_0 for m .²¹³

$$m_0 = (1 / (k-1))(n - (\sum m_j^2 / n)) \quad [4]$$

where n is the total sample size, k is the number of clusters, and m_j is the cluster size in the "jth" cluster with j ranging from 1 to k .

The intraclass correlation coefficients were used to calculate required sample sizes using previously presented methods.^{210;214;215} The Acluster statistical software package was used for the sample size calculations.²¹⁶

Sample size calculation

From the baseline data available, the prevalence of visual acuity <6/18 in one or both eyes was 32%, with an intraclass correlation coefficient of 0.022. The baseline prevalence of binocular visual acuity <6/18 among participants in

the universal screening practices was 12% with an intraclass correlation coefficient of 0.018.

Reidy et al in their recent paper on visual impairment among older people estimated that as much as 70% of the visual impairment could be improved by interventions, mostly spectacles or cataract surgery.³⁵ We planned sufficient power (80%) significant at the 5% level to detect a 30% reduction in the prevalence of visual impairment in one or both eyes (from 32% to 22%), and a 50% reduction in the prevalence of binocular visual impairment overall (from 12% to 6%).

Inviting an average of 150 patients from 20 practices (anticipating a minimum 66% response) would deliver that power. A total of 2000 participants would need to be examined.

Referral criteria

The referral criteria used were identical to those used for the baseline assessments.

The nurses were asked to refer as follows:

1. For anyone with a pinhole vision of less than 6/18 in either eye (logMAR score 0.5 or more), referral to an ophthalmologist was recommended, unless:
 - they had been seen by an ophthalmologist in the previous year;
 - they were registered blind or partially sighted.
2. Anyone with presenting vision of less than 6/18 that improved with pinhole to better than 6/18 was advised to visit an optician.

The letter the nurses used to communicate their findings to the general practitioners is included as appendix 10.

Impaired vision and driving

A question about current driving habits is included in both the National Eye Institute Visual Function Questionnaire and in the VF-14. It was therefore possible that when the research nurses measured visual acuity, they would discover some participants who were driving but whose vision was below the currently recommended level for fitness to drive.

We took advice on this issue from the Medical Unit of the Driver and Vehicle Licensing Agency (DVLA). The current United Kingdom guidelines for fitness to drive state:³⁴

[drivers must be able to] "read in good light (with the aid of glasses or contact lenses if worn) a registration mark fixed to a motor vehicle and containing letters and figures 79.4 millimetres high at a distance of 20.5 metres. In practice this corresponds to between 6/9 and 6/12 on the Snellen chart".

The DVLA advice was to use a cut off point of a binocular logMAR score of 0.4 or more, the equivalent of a Snellen visual acuity of 6/15 or worse.

If the patient scored 0.4 or more when testing both eyes together and had answered that they currently drove, the nurses were instructed to take the following steps:

- tell the patient their vision may fall below the level required by law for driving;
- tell the patient it is their responsibility to inform the Driver and Vehicle Licensing Agency if your findings are confirmed by an optician, ophthalmologist or their GP. The address of the DVLA is given in the information leaflet;
- advise the patient not to drive until they have had their eyes checked by an optician, their GP or an ophthalmologist;
- tell the patient that it is their responsibility not to drive;
- tell the patient that you are informing the GP of your findings;
- refer the patient to their GP using the standard notification letter;

- advise the patient it may be helpful for them to see an optician;
- give the patient the specially designed information leaflet.

3.3 Plan of analysis

Data cleaning

Categorical variables were tabulated and continuous variables displayed graphically to assess the distributions and check for outliers. All missing values were identified. For all outliers and missing values the original data collection forms were reviewed to check the accuracy of the data entry.

Approaches to the analysis

The unit of analysis

In this study the primary target of inference was the individual participant: the intervention was aimed at improving the vision of individual people. The choice of practice as the unit of randomisation was largely made for ethical and logistical reasons. Therefore individual level analyses (taking clustering effects into account in the generation of standard errors and P values) were undertaken and used as the primary method of assessing the trial outcomes. Thus the analysis was dictated by the primary research question of interest.²¹⁷

The need to take clustering into account

Individuals within the same practice (cluster) may be more similar to each other than to individuals in other practices, and thus observations on individuals within a cluster may be correlated. The between cluster variation is in addition to the between individual variation seen in non-cluster trials. Failure to take the clustering effect into account is likely to lead to spuriously low P values and narrow confidence intervals and produce misleading results. All analyses arising from this trial therefore took the clustering effect into account.

Small numbers of clusters per group

The fact there were only 10 practices (clusters) in each arm of the trial limited the complexity of the analyses undertaken. This is because more complex models require reasonable estimates of the between cluster correlation structure as a basis, and the estimates available from only 10 clusters per trial arm are likely to be inadequate. Although it is of course quite possible to fit such models, there is empirical evidence that these models can lead to misleading conclusions when the number of clusters is not large (generally greater than 20 - 40 per intervention group).^{160;162;218;219} The following approaches were considered and rejected as likely to produce misleading or invalid results:

- Ratio estimator and parametric modelling of proportions;¹⁶²
- Generalised estimating equations,²²⁰ mixed effect linear regression²²¹ and multilevel models.²²²

Intention to treat

"Intention to treat" is a strategy for the analysis of randomised controlled trials that compares patients in the groups to which they were originally randomly assigned. The intention to treat approach aims to give a pragmatic estimate of the benefit of a change in treatment policy rather than of potential benefit in participants who receive treatment exactly as planned.²²³ Full application of intention to treat is possible only when complete outcome data are available for all randomised subjects.^{224;225} Clearly not all eligible individuals in randomised practices in this trial were likely to complete an outcome assessment. However, as discussed in the revised CONSORT statement, the key principle is that practices and individuals are analysed in the allocation group to which they were randomised.¹⁷⁹ For this trial, this meant that the analysis included all participants with outcome data available, regardless of whether they actually had a screening assessment at baseline.

As an additional exploratory measure, a per protocol analysis was performed to assess the efficacy of the different screening strategies among participants who adhered completely to the intervention. Such a per protocol analysis was

intended to help explain the effects observed, not in any way replace the intention to treat analysis as the trial outcome.

Analytical methods used

The main analyses were undertaken using the "survey" commands in Stata.^{136,226} The survey commands were specifically designed for the analysis of complex survey data. The number of clusters are taken into account in the degrees of freedom utilised for all significance tests.^{227,228} All variance estimators are multiplied by a correction factor derived from both the number of individual observations and the number of clusters. A key feature of the survey commands is their ability to produce proper variance estimates for subpopulations, using the data structure of the subpopulation to correct variance estimates rather than utilising the corrections based on the whole dataset.

When deriving "survey" regression models, point estimates for coefficients are made using a weighted maximum likelihood estimator. The point estimates are identical to non-clustered estimates (as they intuitively should be). However, the weighted likelihood used is *not* the distribution function for the clustered data, and is therefore called a psuedo-likelihood.²²⁹ The main consequence of this is that likelihood ratio tests for the comparisons of regression models are not valid. Individual Wald tests for coefficients are however valid. Fortunately in the analysis of a randomised trial, each model employed has a single outcome of interest and a single key explanatory factor - the allocated intervention group. The focus of the analysis is on the effect of group allocation on the outcome being modelled. This means that the inability to test different models against one another using likelihood ratio tests is of little importance.

Software

All analyses were carried out using Stata¹³⁶ unless otherwise stated. The World Health Organisation recently developed a software package called Acluster.²¹⁶ Acluster can be used to undertake the adjusted chi-squared and t-

test analyses described above, but does not have the power of Stata to undertake more complex modelling. The main unadjusted analyses were repeated in Acluster as a method of checking the validity of the analyses undertaken in Stata.

Visual acuity

Initially the adjusted chi-squared approach based on a computation of clustering correction factors for each group was used for binary outcomes.²³⁰

It is important to note that this approach cannot take into account any effect of the variable time period between the screening intervention and the outcome assessment. The clustering correction factors are essentially the observed design effect, measures of the inflation in variance due to the clustered design. This approach has been previously used in a range of cluster trials.²³¹⁻²³³

Regression modelling to assess confounding factors and effect modification was then undertaken using logistic regression, modelling the odds ratio for the outcome.

The logMAR scores as continuous measures were modelled as described below for the visual function scores.

Visual function

The visual function outcome, both the composite score and the sub-scale scores, are continuous outcomes on a scale of 1 to 100. In the initial simple analyses, a similar approach to the adjustment described above can be adopted to adjust the two sample t test.^{162;234} The t-test assumes that the cluster specific rates are normally distributed and have equal variances. Extensive simulation research has shown that the t-test is remarkably robust to these assumptions being violated.^{177;235} The t-test is particularly robust when there are equal numbers of clusters in each allocation group, as there are in this particular trial. In addition there is evidence to support the use of the t-test applied to cluster specific rates in trials with as few as three clusters per intervention group.^{177;236}

Multiple regression of the mean scores by group will then be undertaken taking the cluster design into account by using the survey commands in Stata as described above.

Potential confounding factors

The baseline characteristics of the two randomised groups were compared with regard to age and sex. Level of self reported visual problems could be expected to influence the effectiveness of screening for visual problems, either because people perceiving themselves to have a problem may already have sought treatment, or because they may be more likely to accept recommendations for treatment they had not already obtained. Therefore the levels of self reported visual problems in the two randomised groups were also compared.

Time period between baseline screen and outcome assessment was also considered as a potential confounding factor: discussed in more detail below.

In the simple analyses, potential confounding effects could not be assessed. In the logistic regression of binary outcomes and multiple regression of continuous outcomes, exploration of possible confounding effects on the primary trial outcomes was undertaken. The analysis of the primary outcome was repeated while controlling for the potential confounding factor. The unadjusted and adjusted estimates were compared to assess the degree of confounding. If controlling for one or more co-variables substantially affected the effect estimate, then the adjusted estimate would be reported as the main outcome measure.

Effect modification

The trial was not designed to have adequate power to assess the effectiveness of screening for visual impairment in specific sub-groups. The

analysis of possible effect modifiers can however usefully inform attempts to explain the effects or lack of effects of screening seen in a trial. Such analyses were therefore planned as a hypothesis generating approach, not hypothesis testing. For example, if the analysis demonstrated that screening was more effective among people who were socially isolated, this could usefully point towards further research into unidentified visual problems and access to eye services among this group. However, it would be wrong to conclude on the basis of such exploratory analyses that screening could be recommended for one sub-group but not another.²³⁷

The following possible effect modifiers were considered:

(a) Age

The prevalence of visual impairment increase with increasing age. In addition the causes of visual impairment vary with age, in particular with macular degeneration increasing in importance among older age groups. Access to eye services may also be influenced by age. It is therefore quite plausible that the effects of screening could vary by age.

(b) Gender

Even when the effects of age are controlled for, women are at a greater risk of visual impairment than men.^{38;238} Although not specifically known for vision interventions, there is some evidence that gender is associated with adherence to recommendations arising from community-based screening programmes for older people, although the pattern of the association is inconsistent.¹²²

(c) Social isolation

People who are socially isolated may be at greater risk of not accessing the eye health services they need and therefore could potentially gain greater benefit from screening. A question about social isolation was included in the baseline brief screening questionnaire.

In the baseline brief screening assessment, participants were asked the following question: "Do you see friends, neighbours or relatives (other than those you live with)?" Possible answers were "Daily", "2-3 times per week", "Less than twice per week" and "Rarely". The effectiveness of screening was assessed separately for participants who reported seeing other people rarely or less than twice per week and for participants who reported seeing other people twice a week or more.

(d) Self reported visual difficulties at the baseline assessment

Questions about visual problems are not a sensitive measure of detecting visual impairment.¹³⁴ However, people who perceive themselves to have problems with their eyesight may well respond differently to recommendations to see an optician or ophthalmologist following screening.

In the baseline brief screening assessment, participants were asked the following question on vision: "Do you have difficulty seeing newsprint, even if you are wearing glasses". Possible answers were "No difficulty", "A little difficulty" and "A lot of difficulty". The effectiveness of screening was assessed separately for people reporting a lot of difficulty and for people reporting no or a little difficulty.

(e) Time period between baseline screen and outcome assessment

This is considered in the section below.

Time period from screening intervention to outcome

The time period from screening to outcome assessment could have an effect on the outcome of the screening. For example, if the period was very long, it is possible a person could initially have gained some improvement in vision as a result of an intervention following screening, but have subsequently worsened or developed a new cause for visual impairment. Alternatively, a short period between screening and outcome assessment could mean someone was still waiting for an intervention to improve their vision, such as cataract surgery. If

the time period from screening to outcome assessment varied by randomised group, then it could potentially confound the effect of screening. In addition, it is possible that time period from screening to outcome assessment could be an effect modifier, with the effectiveness of screening varying according to the follow-up period.

Analysis of follow-up time

In the logistic regression of binary outcomes and multiple regression of continuous outcomes, the time period of follow-up was considered as a potential confounding factor.

Time period from screening to follow-up was also considered as a potential effect modifier. To maximise power to detect any effect modification, participants were divided into two strata above and below the median time period of follow-up.

CHAPTER 4. PILOT STUDY

Rationale and objectives

Although the National Eye Institute Visual Function Questionnaire^{183;184} (NEI VFQ) is widely used in the United States, we could not identify any published reports of its use with older people in the United Kingdom. We therefore decided to pilot its use, specifically by comparing it with an earlier and shorter visual function questionnaire, the VF-14,¹⁸² that has been used to assess visual function in older people in the United Kingdom.¹⁹³

The visual acuity testing procedure in the outcome assessments of the nested visual screening trial was planned to be identical to the procedure used in the baseline assessment. We therefore decided that the visual acuity testing did not need to be part of the pilot study.

The objectives of the pilot were therefore to:

- Assess the acceptability and ease of use of the National Eye Institute Visual Function Questionnaire compared to the VF-14 questionnaire in older people in the United Kingdom.
- To assess the use of “flashcards” in the administration of the visual function questionnaires (appendix 9).
- Assess the acceptability and clarity of the: invitation letters; patient information leaflets; consent forms and the questionnaire about use of eye services.
- Assess the ease of use of the data extraction forms by the research nurse to extract data about contact with eye services from participants' notes.
- Provide an estimate of how long the assessments take to complete.

Practice and nurse selection

The Leatherhead practice was included in the MRC Elderly Screening Trial. However the practice was unable to take part in the nested visual screening

trial because of the retirement of the research nurse. The research nurse was however happy to undertake a pilot study of the questionnaire.

Ethical approval

Ethical approval for the pilot study was obtained from the East Surrey Local Research Ethics Committee in early February 2000.

Training

Training of the research nurse for the pilot study was undertaken by Martine Donoghue and myself at the Leatherhead practice. Martine Donoghue is a research fellow in the Epidemiology Unit at the London School of Hygiene and Tropical Medicine and has extensive experience in the training and conduct of interviews in the area of vision research.

The research nurse was sent the questionnaires one week before the training day for comments. On the training day the nurse had a two hour training session with both trainers. She then undertook a full assessment with a participant who previously agreed to help on the training day. I observed the assessment. Immediately following the assessment the views of the participant were obtained verbally. There was then a full discussion between the trainers and the research nurse.

Methods

Participants were selected by the research nurse based on the results of the baseline assessments (see below for details). The nurse recruited the participants by invitation letter: a patient information sheet was included. The assessments could take place either in the general practice surgery or in the participants' homes - the location was decided by discussion between the research nurse and the participant.

Results and conclusions

The research nurse saw 16 people during the second half of February 2000. All participants were aged over 75 years and were categorised as follows:

- found to have visual impairment at the baseline screening assessment that improved with use of a pin-hole occluder: therefore advised to see an optician (5 people);
- found to have visual impairment at the baseline screening assessment with *no* pinhole improvement: therefore referred to an ophthalmologist. This group included two people with known severe visual impairment, both of who were registered as partially sighted (total 5 people);
- found to have no visual impairment at the baseline screening assessment (4 people);
- did not attend the baseline assessment (2 people).

The response rate for those asked was high with only one refusal. However the sample was purposefully selected by the nurse as likely to be willing to be involved in the pilot study.

The VF-14 was used in eight of the interviews and the NEI VFQ was used in the other eight. The two different questionnaires were used in around half the people in each of the four groups above.

The median age of participants who completed the VF-14 was 84 years (range 81 to 95). The median age of participants who completed the NEI VFQ was 89 years (range 79 to 91).

Twelve interviews were undertaken in the general practice and four in participants' homes. The nurse reported that the location made no substantial difference to carrying out the assessments.

The mean time taken to complete the assessment was 24.3 minutes (range 20 to 35) for the eight assessments that included the VF-14 and 26.4 minutes (range 20 to 35) for the eight that included the NEI VFQ.

Several amendments were made to the questionnaire as a result of discussions during the training day. Comments made by participants and the research nurse about the questionnaires, the invitation letter and the consent form led to amendments. Other than formatting to improve clarity, no changes were made to the standard questionnaires (the VF-14 and NEI VFQ).

Following the amendments, participants found both interviews acceptable and could understand all the questions.

The research nurse expressed a slight preference in terms of ease of use for the VF-14. However she had no difficulties using the NEI VFQ and felt that it was as acceptable to and as easily understood by participants as the VF-14. The use of “flashcards” was successful: they helped both the research nurse and participants. We therefore decided that use of the National Eye Institute Visual Function Questionnaire with “flashcards” was feasible in the study.

CHAPTER 5. TRIAL EXECUTION

5.1 Ethical approval

The nested trial was approved by the Trial Steering Committee of the MRC Trial of Assessment and Management of Elderly People in the Community in February 1999 (when funding was applied for). Ethical approval was obtained from Trent Multi-Centre Ethics Committee in December 1999. Approval from the 19 Local Research Ethics Committees that cover the 20 practices included in the trial was obtained between December and April 2000.

5.2 Recruitment and sampling of practices and participants

Practice recruitment and sampling

For practical reasons only practices with at least 150 people eligible for inclusion at baseline and who were thought likely to be able to complete another study were invited to participate in the nested vision screening trial. Seventy three practices (out of 106 in the main trial) were invited to participate by letter. Forty practices agreed to participate in the nested vision screening trial. The overwhelming reason for not wanting to participate was that the practices thought that the research nurses in the practice would not have sufficient time to undertake the assessments (stated by 28 practices of 31 giving any reason for not participating). Two practices gave no reason for not wanting to participate.

Among the 40 practices that agreed to participate in the nested vision screening trial, 19 were in the targeted screening arm and 21 were in the universal screening arm of the main trial. The practices in the two groups were of similar size (mean 414 eligible people in the universal screening arm and 422 in the targeted arm). For the main Elderly Screening Trial, randomisation of practices to universal or targeted screening was stratified by SMR levels and Jarman scores in tertiles (see description above). As expected therefore, the distributions of SMR levels and Jarman scores were similar for practices in the two groups.

Because of the similarity of the two groups of practices that agreed to participate, random sampling of practices from each group without further stratification was undertaken. The *uniform* set of commands within Stata were used to randomly select 10 practices from each arm.¹³⁶ Six weeks after selection, prior to any data collection, one of the practices in the universal screening arm withdrew because their research nurse left the practice. A further practice was therefore randomly sampled from the nine remaining practices in the universal screening arm that had agreed to participate.

Comparison of practices included in the nested vision trial with practices not included

The practices included in the MRC Elderly Screening Trial were selected to be representative of the population of Great Britain. It was therefore useful to establish whether the 20 practices included in the nested trial were similar to the 86 practices not included. Table 5.1 presents comparisons between the practices included and those not included.

The table shows that practices selected for inclusion in the nested vision screening trial did not differ substantially from the remaining practices in the MRC Elderly Screening Trial in terms of size, mortality experience or Jarman deprivation score.

Characteristic	Included (20 practices)	Not included (86 practices)	
Mean number of eligible participants	402	405	P=0.94 [#]
SMR tertile (number and %)			
<i>Low</i>	7 (35%)	26 (30%)	
<i>Medium</i>	4 (20%)	31 (36%)	
<i>High</i>	9 (45%)	29 (34%)	P=0.38*
Jarman tertile (number and %)			
<i>Low</i>	5 (25%)	30 (35%)	
<i>Medium</i>	7 (35%)	26 (30%)	
<i>High</i>	8 (40%)	30 (35%)	P=0.70*

[#] P value from t test comparing means

* P value from chi squared test for difference in distribution of characteristics by group

Table 5.1 Comparison of practices included in the nested vision screening trial and those not included

Participant sampling

The power calculation indicated we needed to obtain outcome data on an average of 100 people in the 20 practices. Assuming a 66% response rate, for each practice we would need to invite around 150 people thought to still be alive and still registered with the general practice. From the data available in the main MRC Elderly Screening Trial, it was estimated that around 30% of participants at baseline would have died or moved away by the time invitations for vision outcome assessments would be sent. We therefore randomly sampled 220 participants from the list of those eligible for a baseline assessment in each of the 20 practices. Again, the *uniform* set of commands within Stata were used.

Two practices had less than 220 people eligible for the baseline assessment. In both practices, all people eligible for a baseline assessment were included: 170 in one practice and 210 in the other. Both these practices were in the universal screening group. The final sample therefore included 2140 people in the universal screening arm and 2200 people in the targeted screening arm of the trial. Baseline characteristics of the participating practices and people are described in Chapter 6.

5.2 Study procedure

Invitations

All patients sampled and who were alive and still registered with the practice were invited by letter to take part in the study (appendix 5). An information leaflet about the study was enclosed (appendix 6). Patients were asked to bring any glasses currently worn.

Unless they stated that they did not wish to take part in the study, participants were either telephoned or written to (at an address verified as correct) at least three times before non-response was recorded.

The assessment

Written consent was obtained using a standard consent form (appendix 7).

The assessment was undertaken at the general practice unless the participant was housebound or a home visit meant someone could be seen who would otherwise would not have completed an assessment. The assessment schedule (appendix 8) was in four sections as follows:

Section 1: basic data and a repeat of the vision data collected at baseline

Section 2: visual function questionnaire

Section 3: use of eye services

Section 4: visual acuity

Eligible participants were advised to see an optician by the research nurse. A recommendation that the GP refer the patient to an ophthalmologist was included in the GP information letter as appropriate.

The procedure for people who were current drivers and whose visual acuity appeared to fall below the recommended level is described in detail in Chapter 3.

Data extraction

A data extraction form was completed for all participants who:

1. Reported ever having seen an ophthalmologist.
2. Were eligible for referral to an ophthalmologist following the baseline assessment of the MRC Elderly Screening Trial.

The nurses examined the GP notes and identified all letters which related to eye problems or dealt with referrals to or from any eye specialist.

Record keeping

Research nurses were issued with logsheets for record keeping. Completed assessment schedules, consent forms and data extraction forms were returned to the London School of Hygiene and Tropical Medicine every month.

Data entry

Data from the assessment schedules was double entered by a data entry consultancy company. A 5% sample of records was verified by the investigators. Data from the data extraction forms was coded and entered at the London School of Hygiene and Tropical Medicine.

5.3 Nurse training

A training day was held in London for all research nurses. Twenty four (from a total of 28 in the 20 practices) attended. Two of the remaining four nurses were trained at a second training day in London and two were trained at their practice surgeries.

The training included the following aspects:

- A description of the study.
- Day to day running of study.
- The assessment schedule.
- Measuring visual acuity: ensuring the measurement is taken as far as possible under standardised conditions at the correct distance, with optimum lighting.
- Use of the pinhole occluder.
- Extracting data from patients' notes.

The nurses were issued with a procedures manual (appendix 4).

5.4 Trial monitoring

The trial was monitored by the Trial Steering Committee of the main MRC Elderly Screening Trial. Annual reports of study progress were provided and approved by the Trial Steering Committee and all study procedures were also approved.

CHAPTER 6. RESULTS OF BASELINE SCREENING ASSESSMENTS

6.1 Baseline comparison of randomised groups

The following factors were identified as possibly having an effect on the estimate of effectiveness of screening obtained.

At the practice (cluster) level:

- Jarman score for practice area (a measure of deprivation), because adverse socioeconomic factors are associated with lower use of eye services and with visual impairment;^{109,239-243}
- Standardised Mortality Ratio for practice area, because visual impairment is associated with higher morbidity and with mortality;²⁴⁴⁻²⁵⁰
- Geographical location: because of possible effects on access to eye services.²⁵¹ The MRC General Practice Research Framework has classified the location of participating practices as rural, urban or suburban based on the population density of the geographical area where the practice is based. Clearly this is a rather inexact classification and concordance with access to services will only be partial. However, it is only used to compare balance across the two arms of the trial and therefore does serve a useful purpose.

At the individual level:

- Age;
- Sex;
- Response to the invitation to have a baseline screening assessment;
- Self reported difficulty seeing at baseline;
- Time interval between screening assessment and outcome assessment (therefore time of baseline assessment was compared);
- Social isolation: as described in Chapter 3, social isolation was assessed from a question included in the baseline brief screening

assessment. Participants were asked the following question: “Do you see friends, neighbours or relatives (other than those you live with)?” Possible answers were "Daily", "2-3 times per week", "Less than twice per week" and "Rarely". The results are presented as a binary measure: participants who reported seeing other people rarely or less than twice per week (classified as socially isolated) and participants who reported seeing other people twice a week or more.

In line with CONSORT guidelines,^{179;180} baseline characteristics are presented separately at the practice and participant level as appropriate.

Baseline comparison at the cluster (practice) level

Table 6.1 shows the baseline characteristics at the practice level by randomised group. The two groups of practices were similar with regards to Jarman deprivation score and rural/urban location. The Standardised Mortality Ratios were somewhat higher in the targeted screening group practices, with more practices in the highest tertile and less in the lowest tertile compared with the universal screening group.

Characteristic	Targeted screening group (n=10)	Universal screening group (n=10)	All (n=20)
Jarman tertile			
<i>High</i>	4	4	8
<i>Medium</i>	4	3	7
<i>Low</i>	2	3	5
SMR tertile			
<i>High</i>	6	3	9
<i>Medium</i>	2	2	4
<i>Low</i>	2	5	7
Location			
<i>Urban</i>	2	3	5
<i>Suburban/town</i>	5	5	10
<i>Rural</i>	3	2	5

Table 6.1 Baseline characteristics: practice (cluster) level

Baseline comparison at the individual level

Table 6.2 shows the baseline characteristics at the individual level for all sampled participants (both responders and non-responders) by randomised group. The two groups of participants were similar with regards to age, sex and response rates to the invitation to have a brief assessment.

	Targeted screening group (n=2200)	Universal screening group (n= 2140)	All (n=4340)
Male (%)	797 (36.2%)	833 (38.9%)	1630 (37.6%)
Median age (years)	80.0 years	80.5 years	80.16 years
Ages categories:			
74 to 79	1072 (48.7%)	983 (45.9%)	2055 (47.4%)
80 to 84	646 (29.4%)	671 (31.4%)	1317 (30.4%)
85 to 90	349 (15.9%)	363 (17.0%)	712 (16.4%)
>90	133 (6.1%)	123 (5.8%)	256 (5.9%)
Number and proportion (%) of eligible people completing a baseline brief assessment	1684 (76.6%)	1662 (77.6%)	3346 (77.1%)

Table 6.2 Baseline characteristics at the individual level for all sampled participants

Table 6.3 shows the baseline characteristics at the individual level for all participants who had a baseline assessment by randomised group. The two groups were broadly similar on all measures. There were some differences, for example in the sex distribution and the prevalence of self reported visual problems, but all such differences were small.

Among the 3318 people who completed a baseline brief screening assessment, a total of 28 (0.8%) had a missing or invalid response to the question about difficulty seeing. Of those with missing values, 16 were in the universal screening group and 12 in the targeted group.

Significance tests for the comparisons between the two randomised groups were not carried out because such tests are not useful in deciding whether important baseline imbalance exists.²⁵²

Overall the two groups were similar indicating that the practice randomisation and subsequent sampling of practices and participants had resulted in reasonably well balanced groups. Although the differences were small, there were some baseline differences between the two randomised groups for three factors that could affect the outcome: age, sex and self reported visual problems. Confounding of the trial results by these three factors was therefore assessed (see Chapter 7).

	Targeted screening group (n=1684)	Universal screening group (n= 1662)	All (n=3346)
Proportion male (%)	36.8% (620)	39.8% (661)	38.3% (1281)
Median age (years)	79.9 years	80.3 years	80.0 years
Date of brief assessment			
<i>Median</i>	15 th October 1996	14 th October 1996	14 th October 1996
<i>Earliest</i>	19 th March 1995	28 th March 1995	24 th March 1995
<i>Latest</i>	16 th December 1998	23 rd September 1998	4 th November 1998
Proportion (number) of those responding who reported a lot of difficulty seeing newsprint	9.7% (162)	7.7% (127)	8.64% (289)
<i>missing</i>	12	16	28
Proportion (number) socially isolated*	15.1% (254)	16.8% (279)	15.9% (533)
<i>missing</i>	27	18	45

* see text for how defined

Table 6.3 Baseline characteristics at individual level (results are restricted to people completing a baseline brief assessment)

Other descriptive factors

The data below (table 6.4) are presented in order to provide a fuller description of the type of people in the trial. These factors were not included in the analysis of confounding and effect modification. Consideration of excessive numbers of different factors as potential confounding factors or effect modifiers can lead to spurious significant results and needlessly complicates the analysis.

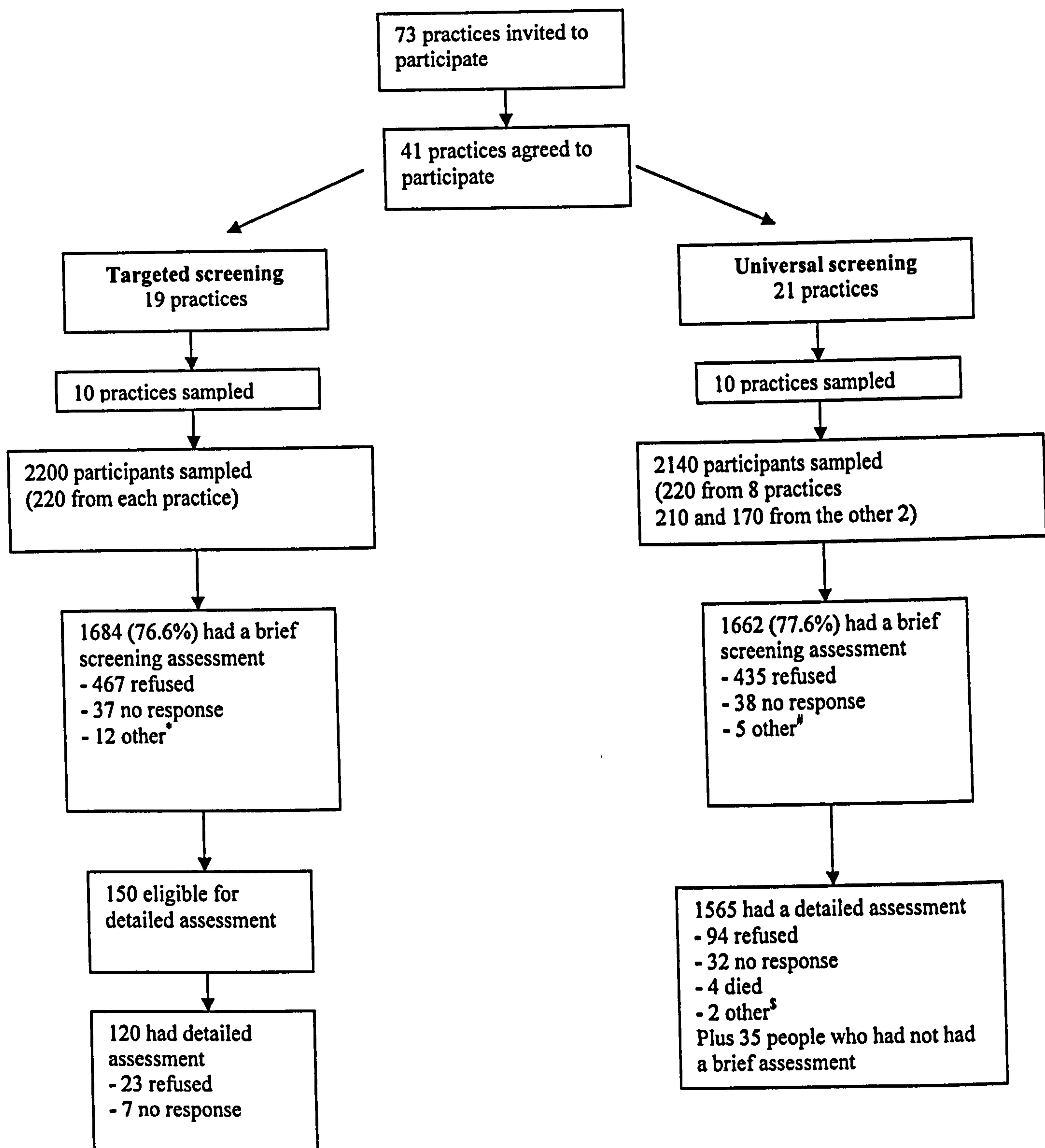
Proportion (number)	Universal screening group (n= 1662)	Targeted screening group (n=1684)	All (n=3346)
Living alone <i>missing</i>	42.9% (713) 18	46.0% (774) 27	44.4% (1487) 45
Reporting no one to call on for help if required <i>missing</i>	3.4% (57) 29	3.0% (49) 41	3.2% (106) 70
Reporting often or always having difficulty making ends meet <i>missing</i>	2.1% (35) 12	2.3% (39) 15	2.2% (74) 27
Reporting one or more falls at home in the previous six months <i>missing</i>	17.7% (290) 19	20.4% (334) 48	18.7% (624) 67
Taking 5 or more medications regularly <i>missing</i>	17.6% (278) 82	18.5% (286) 137	16.9% (564) 219
Reporting often or always feeling sad depressed or miserable <i>missing</i>	8.7% (147) 24	7.5% (124) 30	8.1% (271) 54
Reporting often or always having problems with everyday memory <i>missing</i>	9.0% (152) 10	8.4% (140) 6	8.7% (292) 16

Table 6.4 Additional description of trial participants (results are restricted to people completing a baseline brief assessment)

6.2 Response rate and comparison of responders and non-responders to the baseline brief assessment.

Overall 77.1% (3346/4340) of participants had a baseline assessment. As seen in table 6.2 above, this response rate was similar across the two randomised groups. Of the 994 people who did not have a brief assessment, 902 refused, there was no response after two attempts by letter and/or telephone from 75 people. A further 17 people did not have an assessment for a variety of reasons including administrative error at the research centre or practice (seven people), recorded as having had an assessment by the research nurse but no questionnaire located (four people), and six people who were initially seen by a research nurse but were too ill to undertake an assessment.

The sampling of practices and participants and the baseline assessments undertaken are summarised in figure 6.1.



* 4 too ill, 5 admin error, 3 lost questionnaires

2 too ill, 2 admin error, 1 lost questionnaire

\$ admin error meant 2 people were not invited

Figure 6.1 Practice and participant sampling, and baseline screening assessments undertaken

The individual information about people who did not have a baseline assessment was limited to age and sex. The median age of people who responded was 80.0 years and for people who did not respond was 81.0 years: a difference of only one year. Regarding sex distribution, 38.2% of people who responded and 35.0% of non-responders were male, a non-significant difference of 3.2% (95% confidence interval -4.2% to $+9.1\%$, $P=0.14$).

In conclusion, the response rate to the baseline screening assessment was high, especially for a study in this age group. Respondents were younger than non-responders but the difference was around 1 year. Women were more likely to respond than men, but the difference was small and not significant.

6.3 Vision findings at baseline screening assessment

Brief assessment

In the universal screening group 1662 out of 2140 (77.7%) eligible participants had a brief assessment. In the targeted screening group 1684 out of 2200 (76.6%) eligible participants had a brief assessment.

In the brief assessment participants were asked the following question about vision: “Do you have difficulty seeing newsprint, even if you are wearing glasses”. Possible answers were: “none”; “a little”; or “a lot” (see Chapter 3.1). The results broken down by randomised group are shown in table 6.5.

The proportion of people reporting a lot of difficulty was relatively low given the previous estimates of impaired vision in this age group, with only around 8% of people reporting a lot of difficulty reading newsprint.

	Universal screening (n= 1662)	Targeted screening (n=1684)	All (n=3346)
Proportion (number) of those responding who reported:			
no difficulty seeing newsprint	71.2% (1183)	69.3% (1167)	70.2% (2350)
a little difficulty seeing newsprint	20.2% (336)	20.4% (343)	20.3% (679)
a lot of difficulty seeing newsprint	7.6% (127)	9.6% (162)	8.6% (289)
missing	1% (16)	0.7% (12)	0.8% (28)

Table 6.5 Baseline vision findings at the brief assessment

Detailed assessment

In the universal screening arm all participants were offered a detailed assessment. In the targeted arm, people found to have a pre-specified number and type of problems were eligible for a detailed assessment, as described in Chapter 3.

In the targeted screening group, of the 1684 people who had a brief assessment, 150 (8.6%) reported sufficient problems to be eligible for a detailed assessment. People eligible for a detailed assessment were slightly older: 82.6 years versus 80.6 years. Women were much more likely than men to be eligible for a detailed assessment. Of the 150 people eligible, 111 (74.0%) of them were women compared to 62% of participants in the targeted screening group as a whole being women.

Of the 162 people reporting “a lot of difficulty” seeing newsprint, only 51 (31.5%) were eligible for a detailed assessment. This meant that although 111 other participants reported a lot of difficulty seeing, the number or severity of other problems found at the brief screening assessment were not sufficient to make them eligible for a detailed assessment. In the trial design it would not have been practical to offer a detailed assessment to all people found to have any single problem at the brief screen. Such a policy would have resulted in virtually all participants going on to have a detailed screen – the very procedure being tested in the other arm of the trial. This relates to the issue of screening for visual impairment being one element of a broader multidimensional assessment first discussed in Chapter 2. Thus although self-reported visual problems did contribute to the overall eligibility of participants for a more detailed assessment, the screening strategy adopted in the targeted screening group meant that many people reporting a lot of difficulty seeing did not go on to have a more detailed assessment of their vision.

Response rate to detailed assessment

Universal screening group

In the universal screening group, 1565 people had a detailed assessment from a total eligible of 2140, a response rate of 73.1%. Thirty five people who

had a detailed assessment in this group had not previously had a brief assessment. Of people who had completed a brief assessment, 132 (7.1%) did not go on to have a detailed assessment. Men were slightly more likely than women to have a detailed assessment (75% for men versus 72% for women). Respondents and non-respondents were similar in age (median age of responders 81.1 years versus 81.9 for non-responders).

Targeted screening group

Of the 150 people eligible, 120 completed a detailed assessment, a response rate of 80.0%. Of people eligible, men were more likely than women to have a detailed assessment (response rate for men was 89% versus 76% for women). Responders and non-responders were similar in age (median age of responders 82.3 years versus 83.6 years for non-responders).

Place of detailed assessment

In the universal screening arm, 33.9% (519/1533) of assessments were undertaken in peoples' own homes, the remainder being undertaken at the general practice surgery. Of the 120 people in the targeted arm who had a detailed assessment, a higher proportion were done at home: 58.3% (70/120). People in the targeted arm were identified as eligible for a detailed assessment on the basis of having a range of health problems: hence the higher proportion of people who needed the nurse to visit them at home.

Distance used to measure vision

In the universal screening arm, vision was measured at one metre for 4.4% (69/1565) of participants because of space restrictions. Nearly all these people had their vision measured at home. Four people had their vision measured at one metre in the clinic setting: the reasons for this are unclear. In the targeted screening arm, vision was measured at one metre for 15.0% (18/120) of participants because of space restrictions. This higher proportion reflects the higher proportion of assessments undertaken at home. (These

people are in addition to those people who had their vision measured at one metre because they could not see any letters on the chart at three metres).

Findings at detailed assessment

Findings from the detailed screening assessments by randomised group are presented in table 6.6.

	Targeted screening group	Universal screening group
Number eligible	150	2140
Proportion completing detailed assessment (number)	80.0% (120)	73.1% (1565)
<i>Of people completing a detailed assessment:</i>		
Proportion male (%)	29.2%	40.0%
Median age (years)	82.3 years	81.1 years
Visual acuity < 6/18 in either eye	43.2% (53)	28.8% (451)
<i>Proportion with visual acuity < 6/18 in either eye who had a pinhole assessment</i>	<i>51.0% (27/53)</i>	<i>49.5% (223/451)</i>
Visual acuity <6/18 in either eye that corrected to >6/18 with pinhole correction	6.7% (8)	5.1% (79)
Visual acuity <6/18 binocular	22.0% (26) [#]	12.1% (179) [*]
Visual acuity <6/12 in either eye	60.0% (72)	47.0% (736)
Visual acuity <6/12 binocular	45.8% (54) [#]	34.3% (508) [*]
Owned glasses	87.5% (105)	88.3% (1382)
Eligible for referral to an optician	6.7% (8)	5.1% (79)
Eligible for referral to an ophthalmologist	24.2% (29)	14.1% (220)
Registered:		
blind	3.3% (4)	1.1% (18)
partially sighted	5% (6)	2.2% (35)
data on registration status missing	2.5% (3)	1.5% (24)

^{*} excluding 84 people with missing values

[#] excluding 2 people with missing values

Table 6.6 Baseline findings from the detailed screening assessments by randomised group

Visual acuity

Universal screening group

In the universal screening group, 451 people (28.8%) had a logMAR visual acuity of 0.5 or more in either eye, equivalent to Snellen acuity less than 6/18. One hundred and seventy nine people (12.1%) had presenting binocular vision of logMAR score 0.5 or more (again, equivalent to Snellen acuity less than 6/18). As would be expected, the numbers with a logMAR visual acuity of 0.3 or more (equivalent to Snellen acuity less than 6/12) in either eye or presenting binocular vision were somewhat higher, with over one third of people having a presenting visual acuity of less than 6/12.

Targeted screening group

In the targeted screening group among the 120 people who had a detailed assessment, 53 people (43.2%) had a logMAR visual acuity of 0.5 or more in either eye, equivalent to Snellen acuity less than 6/18. Twenty six people (22%) had presenting binocular vision of logMAR score 0.5 or more. Again, as would be expected, the numbers with a logMAR visual acuity of 0.3 or more (equivalent to Snellen acuity less than 6/12) in either eye or presenting binocular vision were correspondingly higher.

The higher levels of reduced visual acuity among the people in the targeted arm is not surprising. In the targeted screening arm eligibility for a detailed screening assessment was largely based on health related problems detected at the brief assessment, including self reported visual problems.

Pinhole correction

Universal screening group

Of the 451 people found to have visual acuity of less than 6/18 in either eye, 223 (49.5%) had a pinhole corrected visual acuity assessment. The reasons why almost half the people eligible for a pinhole corrected measurement did not have measurements recorded are partly unclear. However, several of the research nurses reported that many participants found the pinhole occluder

difficult to use or said they could not see properly through it. This issue is discussed in more detail in Chapter 9. People with visual acuity less than 6/18 in either eye who did *not* complete a pinhole assessment were still referred to an ophthalmologist.

Of the 223 who did have pinhole corrected visual acuity measurements recorded, vision improved to greater than 6/18 in 79. These people were thus eligible for referral to an optician.

Targeted screening group

Of the 53 people found to have visual acuity of less than 6/18 in either eye, 27 (51.0%) had a pinhole corrected visual acuity assessment. Of these 27, vision improved to greater than 6/18 in 8 people. These people were thus eligible for referral to an optician.

Glasses ownership

Of the 1685 people who had a detailed assessment, overall 1487 (88.3%) reported owning glasses. The proportion of people owning glasses was similar in the universal screening group and among the people from the targeted screening groups who had a detailed assessment (see table 6.6).

Registration as blind or partially sighted

People in the targeted screening arm who were eligible for and completed a detailed screening assessment were more likely to be registered blind or partially sighted than people in the universal screening arm, although the actual numbers are small (table 6.5). Again, the higher levels among the people in the targeted screening group is not a surprising finding because the people who had a detailed assessment in the targeted screening group were a selected minority.

Eligibility for referral to eye services

The criteria for eligibility for referral were as follows:

- (1) For anyone with a pinhole vision of less than 6/18 in either eye (logMAR score 0.5 or more), referral to an ophthalmologist was recommended, unless:
 - they had been seen by an ophthalmologist in the previous year;
 - they were registered blind or partially sighted.
- (2) Anyone with presenting vision of less than 6/18 that improved with pinhole to better than 6/18 was advised to visit an optician.

Universal screening group

In the universal screening group, 79 out of the 1565 people who had a detailed assessment were eligible for referral to an optician (5.1%). A further 220 people (14.1%) were eligible for referral to an ophthalmologist.

Targeted screening group

In the targeted screening group, 8 out of the 120 people who had a detailed assessment were eligible for referral to an optician (6.7%). A further 29 people (24.2%) were eligible for referral to an ophthalmologist.

The people in the targeted screening group who had a detailed assessment had been selected on the basis of having a range of health problems. The higher proportion of visual problems in this group is therefore not surprising.

CHAPTER 7. RESULTS 1: PRIMARY OUTCOME MEASURES

7.1 Response rate to outcome assessment

Progress of outcome data collection

The target and achieved rates of completion of outcome assessments are shown in figure 7.1. The rate of data collection in several practices exceeded the target rate, and all outcome assessments were completed in these practices within several months. There were problems with either changes in the research nurses or excessive workload for the existing research nurses in several other practices, leading to some delays in outcome data collection. The eventual response rates achieved in two practices were particularly low, both of which were reflections of excessive workload for the existing research nurses and inability (in one practice) or unwillingness (in the other practice) to recruit additional research nurses to undertake the remaining assessments. A total of 1807 assessments were completed, 90.4% of the target of 2000.

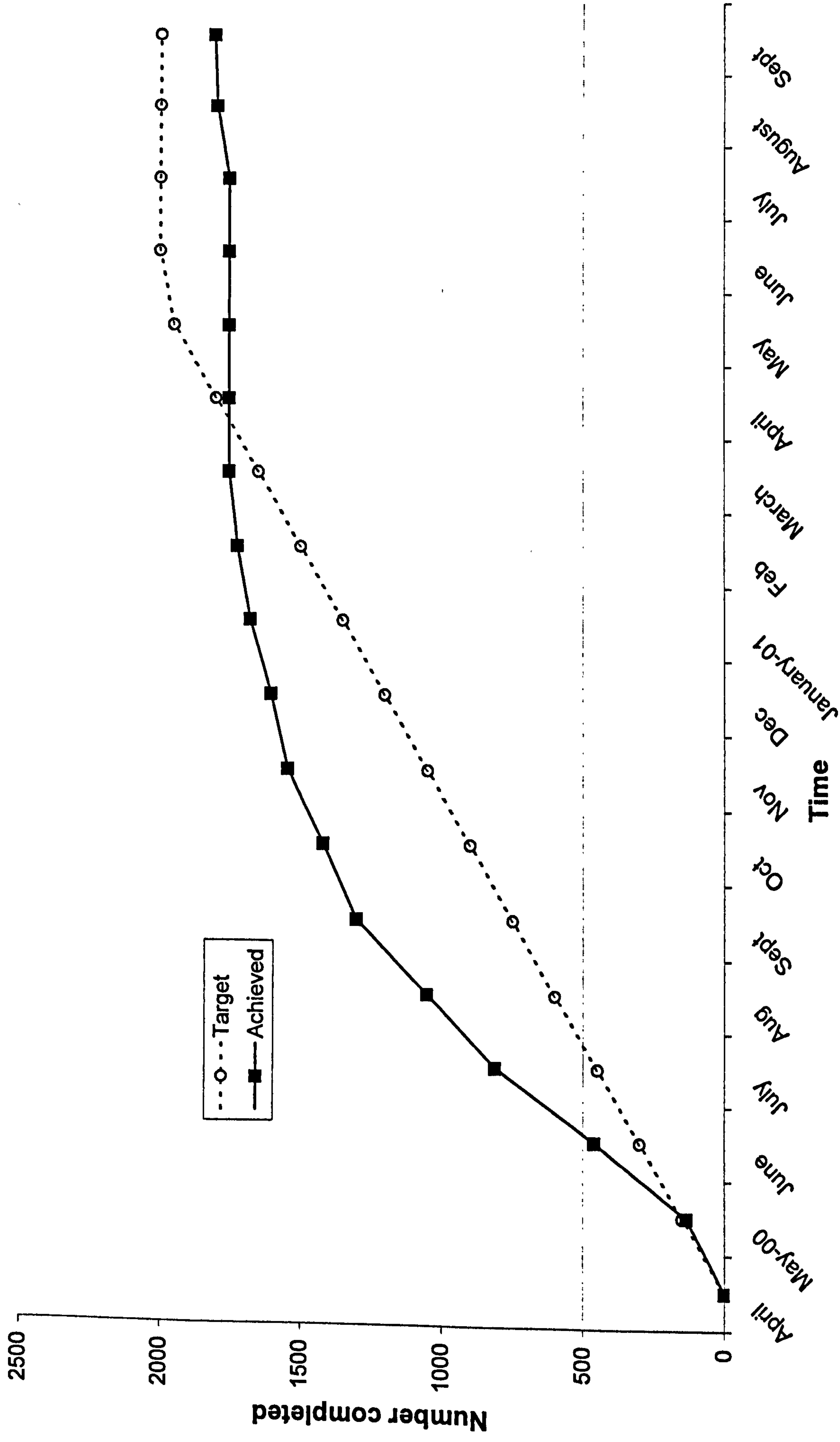


Figure 7.1 Vision screening trial completed assessments: target and achieved

Reasons for non-response

The reasons for non-response to the outcome assessment are given in table 7.1.

Death

As expected in this age group, a high proportion of participants (around one third) had died by the time they were invited for an outcome assessment. 34.4% of people in the targeted screening group had died compared with 33.8% in the universal screening group, a difference of -1.3% (95% confidence interval -6.4% to 3.7%, $P = 0.59$). There was some imbalance in response rate by randomised group, with an overall 5.7% difference between the two groups.

In any such trial the objective is to improve the vision among people who survive, and therefore the response rate needs to be judged amongst survivors. Excluding people who had died, the response rate was 62.8%, which for a trial in this age group is comparatively high. Only 28% of people who could have completed an outcome assessment (i.e. were alive and were not too ill, in hospital or had moved away) refused or did not respond, meaning that 72% of people who *could* have been seen by the study nurses did have an outcome assessment.

After excluding those people who had died before they could be invited to have an outcome assessment, the response rate was 67.8% (829/1432) in the targeted group and 57.9% (829/1432) in the universal screening group (difference -9.9%, 95% confidence interval -19.4% to -0.003%, $P = 0.042$). This difference in response rates could be a potential source of bias in the trial.²⁵³ Low response rates from individual centres are never desirable in a multicentre clinical trial. However in cluster trials, centre specific low response rates are recognised as being particularly problematic because they can lead to imbalance across the randomised groups.¹⁶² Because of the potential bias due to the imbalance in response rates, the issue of response to the outcome assessment is considered in some detail.

Response category	Targeted screening group	Universal screening group	All (%)	Difference (universal – targeted)
Died	757 (34.4%)	708 (33.1%)	1465 (33.8%)	-1.3%
Responded	978 (44.5%)	829 (38.7%)	1807 (41.6%)	-5.7%
Moved away	116 (5.3%)	136 (6.4%)	252 (5.8%)	1.1%
Too ill	42 (1.9%)	37 (1.7%)	79 (1.8%)	-0.1%
In hospital	17 (0.8%)	16 (0.8%)	33 (0.7%)	<0.01%
Refused	266 (12.1%)	404 (18.9%)	670 (15.4%)	6.8%
Not traced	24 (1.1%)	10 (0.5%)	34 (0.8%)	-0.6%
Total	2200	2140	4340 (100%)	

Table 7.1 Response rates and reasons for non-response to the outcome assessment by randomised group

Refusal

A number of factors could have contributed to the difference in refusal rates between the two groups. The two practices in which the eventual response rates were particularly low (due to research nurse workload problems) were both in the universal screening arm. The response rates by different practices are shown in table 7.2.

Clinic code	Eligible participants	Died (%)	Responded	Response rate among those alive at time of invitation (%)
<i>Targeted screening group</i>				
A	220	91 (41.4%)	112	86.8%
B	220	91 (41.4%)	86	66.7%
C	220	76 (34.6%)	86	59.7%
D	220	61 (27.7%)	94	59.1%
E	220	77 (35.0%)	95	66.4%
F	220	66 (30.0%)	117	76.0%
G	220	82 (37.3%)	96	69.6%
H	220	87 (39.6%)	92	69.2%
I	220	55 (25.0%)	114	69.1%
J	220	71 (32.3%)	86	57.7%
Group sub-total	2200	757 (34.4%)	978	67.8%
<i>Universal screening group</i>				
K	220	68 (30.9%)	80	52.6%
L	220	76 (34.6%)	85	59.0%
M	220	57 (25.9%)	87	53.4%
N	220	83 (37.7%)	68	49.6%
O	220	96 (43.6%)	83	66.9%
P	170	44 (25.9%)	75	59.5%
Q	220	75 (34.1%)	47	32.4%
R	220	67 (30.5%)	95	62.1%
S	210	76 (36.2%)	102	76.1%
T	220	66 (30.0%)	107	69.5%
Group sub-total	2140	708 (33.1%)	829	57.9%
Total	4340	1465 (33.8%)	1807	62.9%

Table 7.2 Response rate to outcome assessment by general practice (anonymous alphabetic codes assigned to practices)

In the universal screening group all participants had had a detailed baseline assessment, while in the targeted screening group only a small number of participants had a detailed assessment. People in the universal screening arm may well have remembered the fairly lengthy detailed assessment they had at baseline, and this could have deterred them from re-attending. In addition, the detailed baseline assessment included a visual acuity test. In the invitation to attend for outcome assessment outcome, having a free eye test was highlighted as a benefit of attending. It is possible that some people in the universal screening group recalled having a test of their vision at baseline and hence the prospect of an eye test did not encourage them to attend the outcome assessment.

Other reasons for non-response

The proportions of people who had moved away, were too ill, were in hospital or who could not be traced were quite low and were similar in the two randomised groups.

Comparison of responders and non-responders

Among people still alive at the time of invitation to have an outcome assessment, a comparison of participants who completed an outcome assessment with participants who did not complete an assessment is presented in table 7.3

	Responders (n=1807)	Non-responders (n=1068)	Difference (responders – non- responders)
Median age	82.9 years	84.1 years	1.2 years
Percentage male (number)	36.1% (653)	32.4% (346)	3.7%
Attended baseline screening	86.2% (1558)	70.1% (758)	15.6%
<i>Results for the following variables are also restricted to people completing a baseline brief assessment</i>	n=1558	n=758	
Proportion (number) of those responding who reported a lot of difficulty seeing newsprint at baseline brief screening assessment <i>missing</i>	114 (7.4%) 9	42 (5.6%) 7	1.8%
Proportion (number) socially isolated [#] <i>missing</i>	199 (12.7%) 13	123 (16.2%) 6	-3.5%

[#] see Chapter 3 section 2 for a description

Table 7.3 Comparison of participants who did and did not have an outcome assessment among those alive at time of invitation

Age and sex

Among those people alive at the time of invitation, responders to the outcome assessment were slightly younger than non-responders. Men were slightly less likely than women to have an outcome assessment.

Baseline factors

Not surprisingly, people who had attended the baseline screening assessment were much more likely to complete an outcome assessment than people who had not had a baseline screen.

People who completed a baseline assessment were slightly more likely than non-responders to have self reported visual problems at baseline. The difference was small but is consistent with the idea that people who perceive themselves to have visual problems are more likely to attend for a visual examination. Responders were less likely to have reported being socially isolated at the time of the baseline assessment. The differences between responders and non-responders remained similar after controlling for age.

Visual acuity

In the universal screening arm only, it was possible to assess whether people responding to the outcome assessments differed to non-responders by baseline visual acuity. Because reduced visual acuity is known to be associated with an increased mortality risk,²⁴⁴⁻²⁵⁰ people who did not have an outcome assessment because they had died were more likely to have had visual impairment at baseline. Therefore the analysis was restricted to people who were still alive at the time of invitation to the outcome assessment. Participants who had an outcome assessment were slightly less likely to have had visual acuity <6/18 in one or both eyes at baseline than participants who did not have an outcome assessment (23.0% of responders versus 26.1% of non-responders, difference 3.1%, P=0.33).

These results are discussed in more detail in Chapters 9 and 10.

Comparison of responders by randomised group

The people who completed an outcome assessment are compared by randomised group for various factors in table 7.4

	Targeted screening group n=978	Universal screening group n=829	Difference (universal – targeted screening)
Median age	83.1 years	82.8 years	-0.3 years
Percentage male (number)	35.3% (345)	37.2% (308)	1.9%
Attended baseline screening	85.0% (831)	87.7% (727)	2.7%
<i>Results for the following variables are restricted to people completing a baseline brief assessment</i>	n=831	n=727	
Proportion (number) of those responding who reported a lot of difficulty seeing newsprint at baseline brief screening assessment <i>missing</i>	72 (8.7%) 6	42 (5.8%) 19	-2.9%
Proportion (number) socially isolated [#] <i>missing</i>	90 (10.8%) 9	109 (15.0%) 4	4.2%

[#] see Chapter 3 section 2 for a description

Table 7.4 Comparison of people who completed an outcome assessment by randomised group

Although there were differences between the two groups, these differences were generally small, and more importantly, were consistent with the baseline differences for all participants described in Chapter 6 (see especially table 6.3). Of particular note is that the small difference in self reported visual problems at baseline between the two groups is similar to the difference observed for all participants (table 6.3). Thus there is no good evidence to suggest that the imbalance in response rates between the two randomised groups produced any systematic differences between the two groups which could affect the result of the trial.

The one possible exception is that the proportion of people reporting social isolation at baseline was substantially higher among people in the universal screening group, although the difference was not significant (difference 4.2%, 95% confidence interval 1.9% to 10.2%, $P=0.17$) and was in the same direction as that noted for all participants (table 6.3). Social isolation was already identified as a potential confounding factor in the analysis and thus any effect of this imbalance would be explored.

Location of outcome assessments

The locations where the outcome assessments were undertaken are shown in table 7.5. Just over half the outcome assessments were undertaken at general practice surgeries and just under half were undertaken in participants' homes. The high proportion of home visits reflects the age of the participants and the fact that nurses were instructed to offer to come and visit participants if this would increase the likelihood of the person participating in the outcome data collection.

A total of 47 assessments were undertaken at other locations. Of these, the majority (29) were undertaken in residential homes, 17 were undertaken in nursing homes, and 2 were undertaken at day centres.

There were differences in the distribution of location of outcome assessments across the randomised groups. The lower level of home visiting in the universal screening group was largely explained by the two practices in this group that had lower response rates overall (see above). These two practices had very low home visiting rates, the nurses having concentrated on those assessments that could most easily be done in the time available.

Location	Targeted screening group (n=978)	Universal screening group (n=829)	All (n=1807)
GP surgery	477 (48.9%)	493 (59.5%)	970 (53.7%)
Participant's home	462 (47.2%)	328 (39.6%)	790 (43.7%)
Other*	39 (4.0%)	8 (1.0%)	47 (2.6%)

* see text for details

Table 7.5 Location where outcome assessments were undertaken

Distance used to measure vision

Vision was measured at one metre for 6.2% (112/1807) of participants because of space restrictions, with the proportion being approximately equal in the two arms. All these people had their vision measured at home. (In addition some people had their vision measured at one metre because they could not see any letters on the chart at three metres).

Time period between baseline screening and outcome assessments

The time period in years between the first baseline screening assessment and the outcome assessment was calculated for all participants who had an outcome assessment. For the 236 people who completed an outcome assessment but who did not attend for screening at baseline, the date of invitation for baseline screening was used to calculate the time interval.

The time intervals broken down by randomised group are shown in table 7.6. Results for all people who completed an outcome assessment and who are included in the intention to treat analysis are shown first. The results are then presented for people who both attended the baseline screening assessment they were allocated to and who had an outcome assessment. This is the sub-group of people included in the per-protocol analysis (see below for more details).

The overall median time interval from baseline screening to outcome assessment was around 3.9 years. The figures in the table show that the time periods and their distributions are similar across the randomised groups and were also similar for all participants who had an outcome assessment and for the sub-group who attended the baseline screening.

The median follow-up time in the universal screening group was 3.87 years and in the targeted screening group was 3.90 years.

/		Targeted screening group	Universal screening group	All
<i>All participants who had an outcome assessment</i>				
Number		829	978	1807
Median time interval (IQR) between baseline assessment (or invitation) and outcome assessment		3.90 (3.30 to 4.56)	3.87 (3.41 to 4.31)	3.88 (3.36 to 4.43)
Minimum (1.6) to 2.9 years		143 (14.6%)	107 (12.9%)	250 (13.8%)
3.0 to 3.9 years		382 (39.1%)	371 (44.8%)	753 (41.2%)
3.9 to maximum (5.8) years		453 (46.3%)	351 (42.3%)	804 (44.9%)
<i>Participants who had an outcome assessment who also attended baseline screening[#]</i>				
Number		701	823	1524
Median time interval (IQR) between baseline and outcome assessment		3.88 (3.31 to 4.54)	3.85 (3.41 to 4.28)	3.86 (3.36 to 4.40)
Minimum (1.6) to 2.9 years		119 (14.5%)	82 (11.7%)	201 (13.2%)
3.0 to 3.9 years		324 (39.4%)	335 (47.8%)	659 (43.2%)
3.9 to maximum (5.8) years		380 (46.1%)	284 (40.5%)	664 (43.6%)

^{*} see text for details of how dates were derived
[#] as included in the per-protocol analysis: see below

Table 7.6 Time interval in years between baseline assessment (or invitation) and outcome assessment

7.2 Visual acuity

The results below refer to the intention to treat analysis. The per-protocol analysis is presented in the next section.

Primary outcome measure

The primary outcome measure was the odds ratio of having impaired vision (defined as visual acuity $<6/18$ in one or both eyes) comparing the universal screening group with the targeted screening group. In the targeted screening group 34.7% of people had a visual acuity of less than 6/18 in either eye compared with 37.0% in the universal screening group. The odds ratio was 1.11, 95% confidence interval 0.76 to 1.62, $P=0.58$. The result is shown in table 7.7.

The relative risk ratio was 1.07, 95% confidence interval 0.84 to 1.37, $P=0.58$.

	Targeted screening group n= 978	Universal screening group n= 829	Odds ratio (95% confidence interval)	P value
Visual acuity<6/18 in either eye				
Number (%)	339 (34.7%)	307 (37.0%)	1.11 (0.76 to 1.62)	0.58
Missing	0	0		

Table 7.7 Primary visual acuity outcome (intention to treat analysis)

Confounding

As described in Chapter 3, four factors were considered as potential confounders of the effect of screening: gender, age, levels of self reported visual problems and time period from baseline screening to outcome assessment. Therefore further analyses were undertaken to assess whether controlling for these factors affected the odds ratio estimate for the primary outcome measure.

Assessment of effect of potential confounding factors on trial outcome

The analysis of the primary outcome measure was repeated while controlling for each potential confounding factor in turn. The results are shown in table 7.8. The odds ratio for visual impairment comparing the two randomised groups was virtually identical after controlling for the potential confounding factors. There was no evidence of confounding by any of these factors and therefore the unadjusted estimate was accepted as the most reliable measure.

	Odds ratio risk (95% confidence interval)	P value
Unadjusted	1.11 (0.76 to 1.62)	0.58
Adjusted for: sex	1.12 (0.77 to 1.62)	0.54
age	1.12 (0.75 to 1.68)	0.56
self reported visual difficulty at baseline*	1.18 (0.79 to 1.77)	0.39
time period of follow-up	1.11 (0.78 to 1.59)	0.54

* excludes 258 people without self reported vision at baseline: 249 did not have a baseline assessment plus 9 with missing data

Table 7.8 Odds ratio of visual acuity<6/18 in either eye comparing universal with targeted screening: unadjusted and adjusted for potential confounding factors

Effect modification

As discussed in Chapter 3, the trial was not specifically powered to detect sub-group effects. The analysis of possible effect modifiers was undertaken as an exploratory measure, and as a possible pointer towards future research.²³⁷

The following possible effect modifiers were considered:

- age;
- gender;
- time period between baseline screen and outcome assessment;
- social isolation;
- self reported visual difficulties at the baseline assessment;

See Chapter 3, section 2 for a justification for these factors and a description of the measures used.

The time period of follow-up was divided into three groups as shown in table 7.6.

Age was considered in three groups: 74 to 79 years, 80 to 84 years and 85 years and over.

The odds ratios for the primary outcome stratified by these potential effect modifying factors are shown in table 7.9.

	Odds ratio (95% confidence interval)	P value for interaction*
Overall effect	1.11 (0.76 to 1.62)	
Subgroup:		
Age		
74 to 79	1.16 (0.73 to 1.86)	
80 to 84	1.20 (0.80 to 1.82)	
85 to 96	0.85 (0.47 to 1.55)	0.37
Sex		
Male	1.17 (0.81 to 1.71)	
Female	1.09 (0.71 to 1.68)	0.69
Follow-up period		
Minimum (1.6) to 2.9 years	1.10 (0.64 to 1.90)	
3.0 to 3.9 years	1.12 (0.76 to 1.65)	
3.9 to maximum (5.8) years	1.13 (0.59 to 2.14)	0.95
Social isolation#		
Not isolated	1.09 (0.72 to 1.67)	
Isolated	1.06 (0.53 to 2.13)	0.92
Self reported visual difficulty at baseline		
None or a little	1.18 (0.79 to 1.79)	
A lot	1.12 (0.33 to 3.83)	0.93

* test for heterogeneity of effect across sub-groups: see text for details of how P values were derived
see text for explanation

Table 7.9 Odds ratios for visual acuity<6/18 in either eye comparing universal with targeted screening: potential effect modifiers.

The "P value for interaction" column in table 7.9 shows the P values from the Wald tests for the interaction terms introduced into the models. The null hypothesis of such a Wald test is that the interaction term is the null value: i.e. 1 for an odds ratio.

For each factor the stratum specific odds ratios are very similar to each other and none of the interaction terms approach significance. The one exception is in the oldest age group (85 years and older), where the odds ratio is noticeably lower. However, the confidence intervals are wide and overlap greatly with the estimates from the younger groups. The P value for the interaction term is 0.32. In addition this age group was relatively small (15% of all participants with outcome data). Therefore there is no strong evidence that the effect of the intervention differed in the oldest age group.

Of particular note was that the estimate of effectiveness differed very little by follow-up period.

Per protocol analysis

Participants who completed baseline screening and outcome assessments

All the analyses presented so far are based on the "intention to treat" principal - that is all participants with outcome data available were analysed according to the group they were randomised to, regardless of whether they actually completed the screening assessment they were randomised to. A per protocol analysis in which only participants who adhered completely to the intervention are analysed gives a measure of efficacy of the screening intervention given 100% uptake. Such a measure is of interest when trying to explain the effects observed, but does not serve to replace the main analyses as the measure of effectiveness.

Among the 1807 people who completed an outcome assessment, 1524 had fully complied with the baseline screening intervention. In the universal screening arm, 701 out of 829 people who had an outcome assessment had undergone a detailed visual screening assessment. In the targeted screening arm, out of 978 people who had an outcome assessment, 780 people had a

brief assessment, 51 of whom were eligible for a detailed assessment. Of these 43 people completed a detailed assessment. Therefore 823 people in the targeted screening arm who completed an outcome assessment had undergone baseline screening as per the study protocol.

The numbers of people included in the per-protocol analysis by randomised group are shown in table 7.10.

	Universal screening (n= 829)	Targeted screening (n=978)	All (n=1807)
Number of those with outcome data available who:			
completed a baseline brief assessment	727	780	
eligible for a detailed assessment	All	51	
completed a detailed assessment	701	43	
Underwent baseline screening as specified in the study protocol and therefore included in the per- protocol analysis	701 (84.6%)	823 (84.2%)	1524 (84.3%)

Table 7.10 Adherence to baseline screening assessments among people with outcome data available

Per protocol result

Only the primary outcome measure (the proportion of people with visual acuity <6/18 in one or both eyes) was analysed. In the targeted screening group 278 out of 823 people (33.8%) had a visual acuity of less than 6/18 in either eye, compared with 253 out of 701 people (36.1%) in the universal screening group. The odds ratio was 1.11, 95% confidence interval 0.72 to 1.70, P=0.63. The relative risk was 1.08, 95% confidence interval 0.84 to 1.38, P=0.53.

Other than a slightly wider confidence interval (due to smaller numbers included in the analysis), the per protocol result for the primary outcome measure was virtually identical to the intention to treat analysis.

7.3 Visual function

Method

Description of content of questionnaire

The National Eye Institute 25-Item Visual Function Questionnaire (VFQ-25) was described in Chapter 3. The actual questionnaire used is included in appendix 8.

The questionnaire consists of a set of vision targeted questions representing eleven vision-related constructs. As well as providing a composite overall score, the VFQ-25 generates scores for the following subscales:

- global vision rating (question 2)
- difficulty with near vision activities (questions 5, 6 and 7)
- difficulty with distance vision activities (questions 8, 9 and 14)
- limitations in social functioning due to vision (questions 11 and 13)
- role limitations due to vision (questions 17 and 18)
- - dependency on others due to vision (questions 20, 23 and 24)
- mental health symptoms due to vision (questions 3, 21, 22 and 25)
- driving difficulties (questions 15c and 16)

- limitations with peripheral vision (question 10)
- limitations with colour vision (question 12)
- ocular pain (questions 4 and 19)

Questions 15, 15a and 15b are filter questions designed to determine whether someone has ever driven a car and whether they are currently driving or have stopped. The VFQ-25 also includes an additional single-item general health rating question. This was originally included during the developmental phase of the National Eye Institute VFQ to ensure that researchers had a minimal amount of information about a person's general health status to use as a benchmark against other published samples or cohorts. The single non-vision related health question is still included in the standard questionnaire and was therefore included in the assessment undertaken for this study. However, the score for this question does not contribute to the composite VFQ-25 score.

Scoring

Scoring the VFQ-25 is undertaken using a published algorithm.²⁵⁴ There are two-stages. First, the numeric values from the questionnaire are re-coded onto scales ranging from 0 to 100 for each question. All items are scored so that a high score represents better functioning. This means that scores represent the achieved percentage of the total possible score, e.g. a score of 50 represents 50% of the highest possible score. Second, items within each sub-scale are averaged together to create the twelve sub-scale scores.

Items that are left blank (missing data) are not taken into account when calculating the sub-scale scores. Sub-scales with at least one item answered can be used to generate a sub-scale score. Hence, scores represent the average for all items in the subscale that the respondent answered. The issue of missing data is considered in more detail below.

Composite score calculation

The overall composite score for the VFQ-25 is derived by taking the average of the vision-targeted subscale scores, excluding the general health rating question. By averaging the sub-scale scores rather than the individual items, equal weight is given to each sub-scale, whereas averaging the items would give more weight to scales with more items.

Transformation of data

The VFQ-25 scores were not normally distributed and were negatively skewed. A log transformation was therefore performed with an additional correction factor to reduce the skewness. The test for normalcy on the transformed data was satisfied ($P=0.27$, where the null hypothesis is that the data are normally distributed). All analyses were undertaken using the transformed data with re-transformation of results.

Primary outcome measure

The results of the NEI VFQ-25 composite score by randomised group are shown in table 7.11. For the composite score, the difference between the two groups was small at 0.41, 95% confidence interval -1.68 to 2.50, $P=0.69$.

Sub-scales

The results for the 11 vision sub-scales and for the general health question are presented in Chapter 8.

	Targeted screening, mean (SE)	Universal screening, mean (SE)	Difference (universal - targeted)	95% CI of difference	P value for difference
Number of participants	975	828			
<i>Missing value</i>	<i>3</i>	<i>1</i>			
Composite score	85.62 (0.34)	86.03(0.94)	0.41	-1.68 to 2.50	0.69

Table 7.11 Composite score result for the VFQ-25 by randomised group

Missing and incomplete responses

Of the 1807 people who were seen by a research nurse for an outcome assessment, 1803 completed sufficient items of the VFQ-25 to derive a composite score. Four participants were unable to complete the questionnaire. The research nurses reported that this was because of cognitive impairment (three people) or the participant being too ill to continue with the assessment (one person). Of the four respondents who did not complete the VFQ-25, three were in the targeted screening group and one was in the universal screening group.

The sub-scale and composite scores are derived from non-missing values, thus missing values are ignored. Caution is required in the interpretation of such derived scores if missingness is related to comparison group or if there were high levels of missing values. However, there was no evidence for a differential bias in levels of missing values by randomised group, and the level of missing values overall was low. Even for the sub-scale with the most missing values (colour vision), the total of 15 missing was less than 1% of the total sample. However, because of the potential effect of missing data, a sensitivity analysis was undertaken, repeating the analysis for the primary outcome measure restricted to people with data for all sub-scales.

A total of 140 people out of the 1807 (7.8%) who had an outcome assessment had missing scores for one or more VFQ subscales (excluding the driving subscale among non-drivers). The proportion of people with missing data did not differ significantly by randomised group: in the targeted screening arm 65/829 people (7.8%) and in the universal screening arm 75/903 (7.7%), $P=0.89$ for the test of difference in proportions by randomised group. Restricting the analysis of the composite score to those people with complete data on all sub-scales (excluding driving for non-drivers) had almost no effect on the results (table 7.12).

	Targeted screening, mean	Universal screening, mean	Difference (universal - targeted)	95% CI of difference	P value for difference
Number of participants	975	828			
<i>Participants with missing values</i>	75	65			
Composite score	86.12 (0.42)	86.62 (0.95)	0.50	-1.67 to 2.67	0.64

Table 7.12 Composite score result for the VFQ-25 by randomised group for people with no missing sub-scale scores

Confounding

As described in Chapter 3, four factors were considered as potential confounders of the effect of screening: gender, age, levels of self reported visual problems and time period from baseline screening to outcome assessment. Therefore further analyses were undertaken to assess whether controlling for these factors affected the odds ratio estimate for the primary outcome measure.

The assessment of confounding was undertaken only using the composite score for two reasons. Firstly to avoid excessive numbers of comparisons with the likelihood of spurious "significant" findings. Secondly, there were no good prior hypotheses relating to the NEI VFQ-25 sub-scales to guide the analysis. The same approach to the assessment of confounding was used as for the visual acuity outcomes.

Assessment of effect of potential confounding factors on trial outcome

The analysis of the NEI VFQ-25 composite score was repeated while controlling for each potential confounding factor in turn. The results are shown in table 7.13.

	Difference in means (universal -targeted) and 95% CI of difference	P value [#]
Unadjusted	0.41 (-1.68 to 2.50)	0.69
Adjusted for:		
sex	0.41 (-1.74 to 2.40)	0.75
age	0.37 (-1.56 to 2.29)	0.70
self reported visual difficulty at baseline [*]	-0.49 (-2.82 to 1.84)	0.66
follow-up period	0.43 (-1.67 to 2.53)	0.68

^{*} excludes 258 people with out self reported vision at baseline: 249 did not have a baseline assessment plus 9 with missing data

[#] test of whether the difference in mean scores comparing universal and targeted groups differs significantly from zero

Table 7.13 Difference in mean composite VFQ-25 score comparing universal with targeted screening: unadjusted and adjusted for potential confounding factors

The difference in mean scores between the universal and targeted groups is equal to the regression coefficient for the randomised group variable. This is an estimate of the change in the composite VFQ-25 score for a change in randomised group of one unit, from targeted to universal screening.

The differences in the composite score comparing the two randomised groups were virtually identical before and after controlling for the potential confounding factors. Although controlling for self reported visual problems changed the estimated difference from 0.41 to -0.49, this is actually less than a single point change, and the difference between the universal and targeted screening groups remained non-significant.

Thus there was no evidence of confounding by any of these factors and therefore the unadjusted estimate was accepted as the most reliable measure.

Effect modification

The possible effect modifiers considered were the same as for the visual acuity outcome:

- age;
- gender;
- time period between baseline screen and outcome assessment;
- social isolation;
- self reported visual difficulties at the baseline assessment.

The results for the NEI VFQ-25 composite score stratified by these potential effect modifying factors are shown in table 7.14. The "difference in means" column shows the mean composite VFQ-25 score in the universal screening group minus the mean score in the targeted screening group by sub-group.

The P value is from the test for heterogeneity: that the sub-group results differed significantly from one another: the null hypothesis being that the effect size (difference in means) is the same for each sub-group.

	Difference in means (universal -targeted) and 95% CI of difference	P value for interaction [*]
Overall	0.41 (-1.68 to 2.50)	
Subgroup:		
<i>Age</i>		
74 to 79	0.95 (-1.35 to 3.25)	
80 to 84	-1.36 (-5.35 to 2.63)	
85 to 96	1.36 (-3.01 to 5.72)	0.75
<i>Sex</i>		
Male	-1.53 (-4.21 to 1.14)	
Female	1.39 (-0.96 to 3.73)	0.09
<i>Follow-up period</i>		
Minimum (1.6) to 2.9 years	0.15 (-3.66 to 3.97)	
3.0 to 3.9 years	0.77 (-2.11 to 3.64)	
3.9 to maximum (5.8) years	0.04 (-2.78 to 2.85)	0.80
<i>Social isolation[#]</i>		
Not isolated	0.42 (-2.03 to 2.86)	
Isolated	1.01 (-5.06 to 7.09)	0.84
<i>Self reported visual difficulty at baseline</i>		
None or a little	0.20 (-2.45 to 2.05)	
A lot	-4.48 (-17.96 to 9.00)	0.52

^{*} test for heterogeneity of effect across sub-groups

[#] see text for explanation

Table 7.14 Difference in mean composite VFQ-25 score comparing universal with targeted screening: potential effect modifiers

For each factor the stratum specific difference in means between the randomised groups are similar, the confidence intervals overlap, and none of the interaction terms approach significance. The one exception is for gender, where the P value for interaction is 0.09. However, the difference in the effect between the two genders is small. Therefore there is no good evidence that the effect of the intervention differed in any of the sub-groups. Of particular note was that the estimate of effectiveness differed very little by follow-up period. The sub-group results for the visual function outcome are therefore consistent with the sub-group results for the visual acuity outcome.

Per protocol analysis

Participants who completed baseline screening and visual function outcome assessment

There were four people who had outcome data for the primary visual acuity outcome who had insufficient data to calculate a composite NEI VFQ-25 score: one person in the universal screening group and three in the targeted group. Other than these four people, the people included in the per-protocol analysis for the visual function outcome were the same as those people included in the per-protocol analysis of the visual acuity outcome (table 7.10).

Among the 1803 people who completed the visual function questionnaire part of the outcome assessment, 1521 had fully complied with the baseline screening intervention. In the universal screening arm, 700 out of 828 people who had an outcome assessment had undergone a detailed visual screening assessment. In the targeted screening arm, out of 975 people who had an outcome assessment, 779 people had a brief assessment, 50 of whom were eligible for a detailed assessment. Of these 42 people completed a detailed assessment. Therefore 821 people in the targeted screening arm who completed an outcome assessment had undergone baseline screening as per the study protocol.

Per protocol result

Only the composite score was analysed. The mean score in the universal screening group was 86.44 and in the targeted screening group was 86.11.

The difference (the mean score in the universal arm minus the mean score in the targeted arm) was 0.33, 95% confidence interval -2.13 to 2.80, $P=0.78$. Other than a slightly wider confidence interval (due to smaller numbers included in the analysis), the per protocol result for the visual function primary outcome measure was virtually identical to the intention to treat analysis.

7.4 Summary

Offering visual acuity screening for all people aged over 75 years as part of a multidimensional screening assessment was no more effective at improving either visual acuity or visual function than a strategy of only offering visual acuity screening to people found to have a range of problems at a brief screening assessment. There was no evidence of confounding by age, sex, time period from screening assessment to outcome assessment or levels of self reported visual difficulty at baseline. The effectiveness of universal compared with targeted screening did not vary by age, sex, whether people lived alone or not, frailty, level of self reported visual difficulty at baseline or time period from screening assessment to outcome assessment.

Restricting the analysis to people who completed the screening assessments they had been randomised to produced virtually identical results, strongly suggesting that the lack of effect seen was *not* due to people failing to complete their screening assessments.

The results for visual function and visual acuity were consistent.

The results are discussed in more detail in chapters 9 and 10.

CHAPTER 8. RESULTS 2: SECONDARY OUTCOMES

8.1 Secondary visual acuity outcomes

Missing and incomplete data

A total of 28 people from the 1807 who had outcome assessments had no recorded valid binocular visual acuity measurement, 16 in the targeted group and 12 in the universal screening group. Given the low level of missing values, the approximately equal distribution between the two groups, and the fact that binocular measures were only secondary outcomes, it is unlikely that these missing data would have a substantial impact on the results of the trial.

Pinhole assessments

A total of 554 participants (30.7%) who had an outcome visual acuity assessment were eligible for a pinhole assessment, 316 (32.3%) in the targeted group and 238 (28.7%) in the universal screening group. However only 388 (70.0% of those eligible) completed a pinhole assessment, with similar proportions in the two groups (67.2% in the targeted group and 71.3% in the universal group). The possible reasons why substantial numbers of people eligible for a pinhole assessment did not complete the assessment are discussed in Chapter 9. The incompleteness of the pinhole corrected outcome data would have had no influence on the primary trial outcomes presented in Chapter 7. However, it will have led to an underestimate of the proportion of visual impairment at outcome that could be attributed to refractive error. However, because the missing data was approximately balanced across the two groups, it will not have substantially affected the pinhole corrected visual acuity outcome comparison between the two groups.

Results

Dichotomous outcomes

The results for the secondary visual acuity dichotomous outcome measures are shown in table 8.1.

Using binocular presenting vision less than 6/18 as the outcome produced a slightly different results. The odds ratios indicates a possibly small beneficial effect of universal compared with targeted screening. However, the difference between the two intervention groups are far from significant and the 95% confidence interval ranges from a beneficial effect to a harmful effect of universal screening.

The pinhole corrected visual acuity less than 6/18 in one or both eyes result differs from the non-pinhole corrected, with a small but non-significant benefit shown for people in the universal screening group.

Using a cut-off of visual acuity less than 6/12, the results follow a very similar pattern to that observed for visual acuity less than 6/18.

	Targeted screening group n= 978	Universal screening group n= 829	Odds ratio (95% confidence interval)	P value
Visual acuity<6/18 in either eye Number (%) <i>Missing</i>	339 (34.7%) 0	307 (37.0%) 0	1.11 (0.76 to 1.62)	0.58
Visual acuity<6/18 binocular vision Number (%) <i>Missing</i>	160 (16.6%) 16	114 (14.0%) 12	0.81 (0.59 to 1.12)	0.20
Pinhole corrected visual acuity<6/18 in either eye Number (%) <i>Missing</i>	264 (27.0%) 0	188 (22.3%) 0	0.79 (0.56 to 1.12)	0.18
Visual acuity<6/12 in either eye Number (%) <i>Missing</i>	584 (59.7%) 0	486 (58.6%) 0	0.96 (0.62 to 1.48)	0.83
Visual acuity<6/12 binocular vision Number (%) <i>Missing</i>	351 (36.5%) 16	256 (31.3%) 12	0.79 (0.52 to 1.21)	0.27

Table 8.1 Secondary dichotomous visual acuity outcomes (intention to treat analyses)

Continuous visual acuity outcomes

As previously discussed (Chapter 3), one advantage of using logMAR measures of acuity is that they can be analysed as a quantitative variable. The mean logMAR acuity and the difference between the two groups are shown in table 8.2.

	Targeted screening group mean acuity n=978	Universal screening group mean acuity n= 829	Difference (universal – targeted	95% confidence interval of difference	P value for difference
Binocular presenting acuity <i>Missing</i>	0.228 <i>16</i>	0.211 <i>12</i>	-0.017	-0.065 to 0.032	0.48
Best eye presenting	0.235	0.206	-0.029	-0.078 to 0.020	0.23
Worse eye presenting	0.365	0.346	-0.019	-0.079 to 0.041	0.51
Worse eye following pinhole correction (when performed) <i>Missing</i>	0.329 <i>0</i>	0.309 <i>0</i>	-0.020	-0.066 to 0.025	0.36
Best eye with following pinhole correction (when performed) <i>Missing</i>	0.216 <i>16</i>	0.192 <i>12</i>	-0.025	-0.068 to 0.019	0.25

Table 8.2 Secondary continuous visual acuity outcomes (intention to treat analyses)

The differences in the mean logMAR acuity between the two groups are small and not significant for all the outcomes. All outcomes were slightly better (smaller logMAR average scores) in the universal screening group.

The logMAR score is the log (base 10) of the minimal angle of resolution of the letters read for that score. Because of the irregular progression of letter sizes on a Snellen chart, interpreting differences in logMAR scores in terms of differences in Snellen acuity is not straightforward, because the Snellen equivalent difference depends on the actual acuity level. However, for all outcomes, the differences between the two groups were less than -0.03 logMAR units. To put this in context, a -0.1 logMAR change is equivalent to a change in Snellen score from 6/30 to 6/24, or from 6/15 to 6/12 (see appendix 12). The differences observed were around one third to one fifth of this order of magnitude.

8.2 Secondary visual function outcomes

The secondary visual function outcomes were the NEI VFQ-25 sub-scale scores.

Missing and incomplete data

As described in Chapter 7, a total of 140 people out of the 1807 (7.8%) who had an outcome assessment had missing scores for one or more VFQ subscale (excluding the driving subscale among non-drivers). The proportion of people with missing data was similar for the two randomised groups: 7.8% in the universal screening arm and 7.7% in the targeted arm. However, there was no evidence for a differential bias in levels of missing values by randomised group, and the level of missing values overall was low. Even for the sub-scale with the most missing values (colour vision), the total of 15 missing was less than 1% of the total sample.

Comment on the interpretation of sub-scale results

The NEI VFQ-25 is divided into 12 separate sub-scales. However, four of these sub-scales are based on a single question, and a further four are based on only two questions. In addition the extent to which the NEI VFQ sub-scales actually measure different domains has been questioned.⁸⁵ Because of the large number of sub-scales (and hence the likelihood of false positive results due to multiple comparisons), the developers of the NEI VFQ advise a priori specification of those sub-scales that are of most relevance to the intervention or effect being measured.²⁰³ However in this study all possible causes of reduced vision were included and participants potentially could have received a broad range of interventions. We therefore had no specific sub-scales we wished to focus on as outcomes, hence the specification of the composite score as the primary outcome measure. These factors (discussed in more detail in Chapters 9 and 10) mean that caution is required when interpreting the results for the different sub-scales.

Results

The differences for all 11 vision sub-scales and for the general health question are shown in table 8.3. All differences between the two randomised groups were very small and none were significant.

Sub-scale	Targeted screening, mean (SE)	Universal screening, mean (SE)	Difference (universal - targeted)	95% CI of difference	P value for difference	Participants with missing values
General health	51.49 (1.95)	52.54 (1.71)	1.05	-4.38 to 6.48	0.69	4
General vision	72.08 (0.58)	71.14 (1.06)	-0.95	-3.48 to 1.59	0.44	4
Ocular pain	87.47 (0.87)	87.97 (1.03)	0.50	-2.34 to 3.32	0.72	5
Near activities	82.3 (0.59)	82.8 (1.53)	0.5	-2.8 to 3.8	0.75	7
Distance activities	83.66 (0.78)	83.63 (1.35)	0.02	-3.30 to 3.24	0.98	10
Social functioning	91.73 (0.41)	92.91 (0.82)	1.18	-0.73 to 3.09	0.21	11
Mental health	86.20 (0.83)	87.11 (1.34)	0.91	-2.41 to 4.22	0.57	5
Role difficulties	83.02 (0.68)	83.41 (1.27)	0.39	-2.62 to 3.41	0.79	5
Dependency	90.46 (0.64)	91.36 (0.85)	0.90	-1.34 to 3.14	0.41	11
Driving [#]	78.59 (1.82)	78.42 (1.96)	-0.18	-5.76 to 5.42	0.95	11
Colour vision	95.16 (0.53)	95.22 (0.92)	0.06	-2.16 to 2.29	0.95	15
Peripheral vision	88.07 (0.45)	89.33 (1.26)	1.27	-1.5 4 to 4.07	0.36	14

[#] score and number missing based on 555 people who currently drive or who gave up driving mainly because of eyesight and were therefore eligible for the driving sub-scale

Table 8.3 Sub-scale results for the VFQ-25 by randomised group.

8.3 Summary

The results for the secondary outcomes were consistent with those of the primary outcomes, showing that offering visual acuity screening for all people aged over 75 years as part of a multidimensional screening assessment was no more effective at improving visual function than a strategy of only offering visual acuity screening to people found to have a range of problems at a brief screening assessment.

Following pinhole correction of refractive error, the proportion of people with a visual acuity of less than 6/18 in either eye fell by around 10%. The pinhole corrected vision is a better reflection of reduced visual acuity likely to be due to eye disease rather than refractive error, although it is likely that not all refractive error would have been corrected. The resulting proportion of people with a corrected visual acuity of less than 6/18 in either eye was somewhat lower in the universal screening arm, but the difference between the two groups was not significant.

The binocular presenting acuity results also showed that the proportion of participants with reduced vision was slightly lower in the universal screening arm. However, again the differences were not significant and were compatible with random variation in the results obtained.

The conclusions from the analysis of visual acuity as a continuous measure were the same: a very small but non-significant difference in favour of the universal screening group.

For the NEI VFQ-25 sub-scale results, there were no significant differences between the two groups and all the differences observed were small.

The results are discussed in more detail in Chapters 9 and 10.

CHAPTER 9. RESULTS 3: EXPLANATORY AND PROCESS MEASURES

9.1 Approach to the analysis

An approach to analysing the effectiveness of different stages of a preventive intervention was developed²⁵⁵ and subsequently updated by the Canadian Task Force on the Periodic Health Examination.²⁵⁶ This approach is similar to the approach used in Chapter 1 (section 2) of this thesis, the review of non-trial literature around screening older people for impaired vision. A causal pathway is mapped out identifying different elements of the intervention package and considering the effects of each stage separately.

For the intervention assessed in this trial these stages were:

- a) Accuracy and validity of the screening test used.
- b) Levels of visual impairment found.
- c) Proportion of people with visual impairment already known to the eye services.
- d) Eligibility for referral.
- e) Causes of visual impairment found.
- f) Likely effectiveness of interventions for visual impairment found.
- g) Uptake and consequences of referrals.
- h) Reasons for non-uptake of referrals or interventions.

9.2 Explanatory factors

Accuracy and validity of the screening test used

A possible drawback of the previous trials of multidimensional screening of older people that included a screen for visual problems was that all trials had used a self-reported measure of visual problems as a screening tool. In the universal screening arm of this trial, all participants had a visual acuity measurement. There is no “gold standard” against which to judge visual

acuity. However this does not mean that visual acuity has no possible shortcomings as a screening tool.

Measurement error

There was likely to be some measurement error in the screening visual acuity assessments undertaken at baseline. Although the nurses all received the same training and were all observed undertaking measurements during the training session, it is likely that there were some inconsistencies in the procedures adopted by different nurses, as well as a varying level of errors made. Although the research nurses were asked to take steps to ensure adequate lighting, lighting levels were not standardised. In the clinic setting it is likely that lighting levels were adequate. However, around one third of screening assessments were undertaken in participants' homes where lighting levels are likely to have been more variable.⁶⁴

The proportion of people who had their vision measured at one metre because of space restrictions was small at around 5% overall. Although the chart used was designed to be able to be used at one metre, there is a small loss of accuracy of measurement.⁶⁷

Some impression of the specificity of the visual screening measurements can be gained by looking at those people found to have visual impairment who were eligible for referral to an ophthalmologist. For those people with available data who were eligible for referral, only 3 out of 116 (2.6%) had no previously diagnosed eye disease.

The pinhole test

The pinhole occluder was used to distinguish refractive error as a likely cause of visual impairment found. However, some older people find the pinhole occluder difficult to use.⁷¹ This may be because one effect of the pinhole occluder is to greatly reduce the amount of light reaching the eye, and older people are known to already have reduced retinal illumination.²⁵⁷

As seen in section 6.3, only around half the participants who were eligible to have a pinhole corrected visual acuity assessment actually had measurements recorded by the research nurses. The reasons why around half the people eligible did *not* have pinhole corrected measurements

recorded are unclear. However, several of the research nurses reported that many participants found the pinhole occluder difficult to use or said they could not see properly through it. Given that the pinhole occluder led to substantial visual improvement in around one third of the people who *did* have pinhole corrected acuity measurements recorded, it is likely that refractive error as an easily correctable cause of visual impairment was under detected. People with visual acuity of less than 6/18 in either eye who did not have a pinhole assessment were referred to an ophthalmologist, and would have had refractive error diagnosed in the ophthalmology clinic.

Visual acuity as a measure of the need for interventions

As discussed in Chapters 1 and 3, reduced visual acuity may not accurately reflect “need” for measures to improve vision. However, to date the visual function indices that have been shown to be valid⁸⁵ would be too long to be feasible screening tools. The development of screening tools that are better able to measure the impact of vision on peoples’ lives are needed.

Criteria for referral following screening

The criteria were chosen at the time the main trial was designed in the early to mid-1990s. The referral criteria were an attempt to ensure that people referred were those likely to benefit from interventions. Therefore people who were already registered as blind or partially sighted and people who had seen an ophthalmologist in the past year were not eligible for referral on the grounds that they were unlikely to benefit from a new referral.

As discussed in Chapter 1, recent work has shown that the levels of vision at which people have difficulties with everyday tasks depend on the task, indicating the limitations of trying to define a level of vision as disabling.^{81;83} Although somewhat arbitrary (being dependent on the context of the health system), a pragmatic action threshold set by considering the level of vision below which a person is likely to be offered interventions to improve their vision provides a coherent method of determining referral criteria.

Clearly referral was appropriate for the people who attended ophthalmology clinics and who benefited from cataract extraction (16 out of 41 people

referred and who had outcome data available). For the other people who were referred to and attended ophthalmology clinics, a range of new diagnoses were made. Although visual acuity was not improved, there is no evidence to suggest that the referrals were inappropriate.

Many of the people advised to see an optician obtained new lenses (24 out of 40 people with outcome data available) and their level of uncorrected refractive error was reduced, again suggesting that their referrals were appropriate.

Levels of visual impairment found

As reported in Chapter 6, a substantial proportion of participants were found to have disabling levels of visual loss at the baseline screening assessment (table 9.1). In the universal screening group, 28.8% (451/1565) of people had a visual acuity of less than 6/18 in either eye, and 12.1% (179/1481, excluding 84 people with missing values) had a binocular acuity less than 6/18. The nested vision screening trial included only a sample of the practices participating in the MRC Trial of the Assessment and Management of Elderly People in the Community, and a sample of people from within these practices. The levels of visual impairment found in the nested vision screening trial were similar to those found in the main trial, indicating that a representative sample was included in the nested vision screening trial.²³⁸

Taking into account methodological differences in the measurements made and the fact that people in long-term residential care or with terminal disease were excluded, the levels are similar to prevalence estimates from previous surveys in the United Kingdom.^{35;37;38}

In the targeted screening group, 44.2% (53/120) of people who had a visual acuity screening assessment had an acuity less than 6/18 in either eye, and 22.0% (26/118, excluding two people with missing values) had binocular acuity less than 6/18. As already explained, the higher levels of visual impairment in the small sub-group from the targeted screening group are not surprising, given that these people were selected for a detailed assessment

on the basis of having a range of problems found at the brief screening assessment.

As would be expected, the numbers of people with visual problems found using a cut-off of Snellen acuity less than 6/12 were substantially higher.

	Targeted screening group	Universal screening group
Number eligible	150	2140
Proportion completing detailed assessment (number)	80.0% (120)	73.1% (1565)
<i>Of people completing a detailed assessment:</i>	<i>n=120</i>	<i>n=1565</i>
Visual acuity < 6/18 in either eye	43.2% (53)	28.8% (451)
<i>Proportion with visual acuity < 6/18 in either eye who had a pinhole assessment</i>	<i>51.0% (27/53)</i>	<i>49.5% (223/451)</i>
Visual acuity <6/18 in either eye that corrected to >6/18 with pinhole correction	6.7% (8)	5.1% (79)
Visual acuity < 6/18 binocular	22.0% (26) [#]	12.1% (179) [*]
Visual acuity <6/12 in either eye	60.0% (72)	47.0% (736)
Visual acuity <6/12 binocular	45.8% (54) [#]	34.3% (508) [*]
Owned glasses	87.5% (105)	88.3% (1382)

^{*} excluding 84 people with missing values

[#] excluding 2 people with missing values

Table 9.1 Summary of baseline vision findings from the detailed screening assessments by randomised group

Proportion of people with reduced vision already known to the eye services

Glasses ownership among people with probable refractive error

As shown in table 9.1, the overall level of glasses ownership was high (88%). Among the sub-group of people found to have reduced acuity (<6/18) in either eye that corrected with use of the pinhole occluder, levels of glasses ownership were similar to levels among the whole sample (table 9.2). Participants were asked to wear their usual glasses for the visual acuity screening assessment. Thus in spite of the high proportion of people already owning glasses, there was evidence that many still had refractive error that could be improved using a pinhole occluder, suggesting their glasses were inadequate.

Contact with ophthalmology services

In the universal screening group, 28.8% of those people found to have visual acuity less than 6/18 in either eye reported that they had seen an ophthalmologist in the previous year (table 9.2). In the targeted screening group, the corresponding figure was lower at 15.1%. This difference may partly be a reflection of the higher levels of registration as blind or partially sighted in the targeted group. People who had been registered as blind or partially sighted more than one year before the screening assessments would be unlikely to have seen an ophthalmologist in the previous year.

Registration as blind or partially sighted

The numbers of people who reported being registered blind or partially sighted are shown in table 9.2. The criteria for registration in the United Kingdom are based on accurate best corrected acuity measurements and visual field assessments. Given that only around half the people with reduced vision actually had a pinhole assessment, that the pinhole occluder is only a crude way of correcting possible refractive error and that visual fields were not measured, we could not fully assess the accuracy of this self-reporting.

In summary, taking the universal screening arm as representative of the population screened, among the people with visual impairment that did *not*

appear to be due to refractive error, 35.0% (130/372) of people had seen an ophthalmologist in the previous year and a further 14.2%% (53/372) were registered blind or partially sighted.

	Targeted screening group n=53	Universal screening group n=451
Visual acuity corrected to >6/18 with pinhole assessment	15.1% (8)	17.5% (79)
<i>Proportion who owned glasses among people whose vision corrected with pinhole</i>	75.0% (6/8)	90.0% (71/79)
Seen by ophthalmologist in previous 12 months	15.1% (8)	28.8% (130)
Registered:		
blind	7.5% (4)	4.0% (18)
partially sighted	11.3% (6)	7.8% (35)
data on registration status missing	5.7% (3)	5.3% (24)

Table 9.2 Contact with eye services by randomised group among people found to have visual acuity less than 6/18 in either eye at baseline screening

Eligibility for referral

Among people found to have visual acuity of less than 6/18 in either eye, many were not eligible for referral to an ophthalmologist for a variety of reasons. These are shown in table 9.3 along with the numbers eligible. Note that the column totals do not add up because people can be in more than one category. For example someone could have reduced acuity visual that corrected to greater than 6/18 with a pinhole occluder and therefore be eligible for referral to an optician, but also have seen an ophthalmologist in the previous 12 months.

Universal screening group

In the universal screening group, 451 out of 1565 people who had a screening assessment had a visual acuity less than 6/18 in either eye. From the 1565 people who had an assessment, 220 (14.1%) were eligible for referral to an ophthalmologist and 79 (5.1%) were eligible for referral to an optician.

Targeted screening group

In the targeted screening group, 53 out of 120 people who had a screening assessment had a visual acuity less than 6/18 in either eye. From the 120 people who had an assessment, 29 (24.2%) were eligible for referral to an ophthalmologist and 8 (6.7%) were eligible for referral to an optician.

The people in the targeted screening group who had a detailed assessment had been selected on the basis of having a range of health problems. The higher proportion of visual problems in this group is therefore not surprising. The total number of referrals in the targeted arm was however still low, reflecting the small proportion of participants in the targeted arm who completed a detailed assessment.

	Targeted screening group n= 53	Universal screening group n= 451
<i>Reason why not eligible for referral to ophthalmologist</i>		
Registered blind or partially sighted	10 (18.9%)	53 (11.8%)
Seen by an ophthalmologist in previous 12 months	8 (15.1%)	130 (28.8%)
Acuity >6/18 with pinhole correction	8 (15.1%)	79 (17.5%)
<i>Eligible for referral</i>		
To ophthalmologist	29 (54.7%)	220 (48.8%)
To optician	8 (15.1%)	79 (17.5%)

Note column totals do not add up because people can be in more than one category

Table 9.3 Eligibility for referral from baseline assessment by randomised group among people found to have visual acuity less than 6/18 in either eye at baseline screening

Causes of visual impairment found

Refractive error

Proportion attributable to refractive error

In the universal screening group, of the 451 people with visual acuity less than 6/18 in either eye, 79 (17.5%) had a pinhole corrected acuity of greater than 6/18, suggesting that the reduced vision could be at least partly attributed to refractive error (table 9.4). In the targeted screening group, the corresponding proportion was 8/53 (15.1%). As discussed above, the proportion attributable to refractive error will have been under-estimated because many eligible people did not complete a pinhole assessment.

Other causes

Sources of data

Of the 249 people eligible for referral to an ophthalmologist following the baseline assessment, data on the likely causes of the visual loss found on screening came from two sources. Firstly, the search of patient general practice records undertaken by the study nurses at the time of the outcome assessment in the vision screening trial. All letters and entries in the patient records that were about eyes were extracted. Diagnoses and treatments recorded both before and after the date of the baseline assessment were summarised using a structured data extraction form (appendix 11). The data about diagnoses and treatments following the baseline screening are presented below in section (g). The second source of data about the likely causes of the visual loss was from an additional study that was undertaken by Jenny Evans and colleagues (Moorfields Eye Hospital). This study (referred to below as the *Causes of visual impairment study*) aimed to identify the causes of visual impairment of participants in the MRC trial of the assessment and management of older people in the community. For the causes study, in addition to the data extracted from letters from eye services which were included in general practitioner notes, a one-page questionnaire was sent to the hospital ophthalmologist who had last seen the patient. This questionnaire was in the form of a check-list that covered: age-related macular degeneration, cataract, glaucoma, diabetes, myopic degeneration, or other (asked to specify). The ophthalmologist was asked to rank, if possible, any conditions ticked in order of their contribution to visual loss.

Both sources of data were incomplete for a variety of reasons, so that even after combining information from the two sources, the cause of visual impairment could not be identified for a substantial number of people eligible for referral.

Of the 249 people eligible for referral to an ophthalmologist, 108 (43.4%) had died before having an outcome assessment, meaning that general practice notes were not available to the study nurses (the high mortality rate is discussed in more detail below in Chapter 10). An additional 10 people had moved away. Although our original intention had been to collect data from the medical records of all remaining participants, in practice the data extraction from notes was only undertaken for people who completed an outcome assessment. The main reasons for this restriction were high workload and time constraints for the study nurses. We asked them to focus on achieving a high uptake rate for outcome assessments, to undertake notes searching at the time of outcome assessment for participants, and go on to search the notes of people who did not complete an outcome assessment when they had time. In practice the latter did not happen. A secondary factor raised by some of the research nurses was that they did not feel comfortable searching the medical records of people who had refused to participate in the outcome data collection part of the study. In spite of the fact that we had ethical approval to search the medical records of all people who were screened at baseline, it was difficult to override the nurses' reluctance on this issue.

The *Causes of visual impairment study* only included people from the universal arm of the main trial. The cause of visual impairment was identified for around 70% of visually impaired participants. However, a limitation in using data from the *Causes of visual impairment study* was that the study only attempted to assess the cause of visual impairment in those people found to have a pinhole corrected visual acuity of less than 6/18 in their *better* eye at the baseline assessment. Eligibility for referral to an ophthalmologist was based on a corrected visual acuity of less than 6/18 in *either* eye, meaning that many people who were eligible for referral to an ophthalmologist were not eligible for inclusion in the *Causes of visual impairment study*. Conversely, many of the people with data on diagnoses

available from the causes of visual impairment study had seen an ophthalmologist in the previous year or were registered blind or partially sighted, and were therefore not eligible for referral to an ophthalmologist in the trial.

Causes identified

Of the 75 people eligible for referral to an ophthalmologist at the baseline screening assessment who also completed an outcome assessment, data about eye disease and treatments were extracted from the general practice records for 72 people (96.0%). For three people there was no record of them ever having been seen by any eye services, and this accorded with their response to the outcome assessment questionnaire. The cause of visual impairment at baseline could be identified for a further 41 people from the causes of visual impairment study. Therefore the likely cause of visual impairment at baseline could be identified for a total of 113/249 (45.4%) of people eligible for referral to an ophthalmologist.

The causes of visual impairment broken down by randomised group are shown in table 9.4.

Cause identified	All number (%)	Targeted screening group number (%)	Universal screening group number (%)
<i>Total eligible for referral to ophthalmologist following baseline screen</i>	249	29	220
Eligible for referral and data on cause of visual loss available	113 (100%)	15 (100%)	98 (100%)
Age related macular degeneration (AMD)	28 (24.7%)	4 (26.7%)	24 (24.5%)
Cataract with no record of extraction	19 (16.8%)	2 (13.3%)	17 (17.3%)
Cataract with record of previous extraction	18 (15.9%)	2 (13.3%)	16 (16.3%)
Cataract with uncertain record of previous extraction	22 (19.5%)	2 (13.3%)	20 (20.4%)
Diabetic eye disease	1 (0.9%)	0	1 (1.0%)
AMD and cataract	14 (12.4%)	2 (13.3%)	12 (12.2%)
AMD and other	2 (1.8%)	1 (6.7%)	1 (1.0%)
Cataract and other	2 (1.8%)	0	2 (2.0%)
Other	4 (3.5%)	1 (6.7%)	3 (3.1%)
Never seen by eye specialist	3 (2.6%)	1 (6.7%)	2 (2.0%)

Table 9.4 Likely causes of visual impairment among people eligible for referral to an ophthalmologist at baseline by randomised group (for those with data available)

For people with a diagnosis of cataract, an attempt was made to distinguish between those people who had previously had a cataract extraction and those who had not. However, as can be seen from the table, this was not always entirely clear from the information extracted from the notes. Where there was uncertainty people were classified as unclear.

The pattern of diagnoses are not typical of all older people with reduced vision. This is because the eligibility criteria for referral to an ophthalmologist excluded people who were registered blind and partially sighted, and also excluded people who had seen an ophthalmologist in the past 12 months. The proportions of people with age related macular degeneration, and to a lesser extent diabetic eye disease and glaucoma, are therefore lower than among the general population of people in this age group with visual impairment.^{35;37;258}

Likely effectiveness of interventions for visual impairment found

The effectiveness of interventions for reduced vision were summarised in the literature review presented in Chapter 1, section 2. As discussed there, while it has been estimated that over 70% of the visual impairment present in people aged 65 and over is potentially remediable,³⁵ this high proportion may not apply to people identified in this trial. In the study by Reidy et al, visual impairment was defined as binocular visual acuity less than 6/12. The lower cut off to define visual impairment in this trial (visual acuity less than 6/18 in either eye), and the older age of participants meant that visual problems were more likely to be due to serious eye disease such as macular degeneration or glaucoma and less likely to be due to refractive error or cataract than in the population identified by Reidy et al.³⁵

Uptake and consequences of referrals

As explained above in section (e), detailed information about the results of referrals was only available for people who completed an outcome assessment.

Optician referrals

As discussed in Chapter 3, “referral to an optician” actually meant that the participant was advised to visit an optician. Data about the uptake and consequences of optician referrals are derived entirely from self-report. This was because it would have been difficult to collect data about participants from optician records for two reasons. Firstly participants could choose to go to any optician(s) they liked in any geographical location. Secondly, there would be no record of contact with an optician in the participant’s medical record unless the optician made a specific recommendation to the general practitioner that the patient be referred to an ophthalmologist. The totally self-reported nature of the data about optician referrals therefore means that some caution should be exercised in interpreting the data.

Of the 79 people eligible for referral in the universal screening arm, 36 people (45.6%) completed an outcome assessment and had data about the result of the referral available. In the targeted screening arm, of the 8 people eligible for referral, 4 (50%) completed an outcome assessment and had data about the result of the referral available.

The results of the referrals are shown in table 9.5.

As seen previously, there was a high level of ownership of glasses among those eligible for referral to an optician even before the baseline screening assessment. The proportion of people advised to see an optician who reported attending an optician at least once after the baseline screening was high at 80% (32 out of 40). Clearly many of these people may have attended an optician anyway even without screening. A total of 14 people when specifically asked remembered going to the optician as a result of being advised to do so at the baseline screening assessment. Of the remaining people, 14 said they went regularly already, and 4 could not recall whether the reason they went had anything to do with the baseline assessment.

Quite high numbers of people had had new glasses or lenses recommended since the baseline assessment. By the time of the outcome assessment, all people eligible for referral to an optician at baseline owned glasses. The uptake and consequences of optician referrals are shown in table 9.5.

	All number (%)	Targeted screening group number (%)	Universal screening group number (%)
<i>Total eligible for referral to optician following baseline screen</i>	87	8	79
Eligible for referral to optician and outcome data available	40 (100%)	4 (100%)	36 (100%)
Owned glasses at baseline screen	38 (95%)	3 (75%)	35 (97.2%)
Attended an optician following the baseline assessment	32 (80%)	3 (75%)	29 (80.1%)
<i>Remembered going to the optician as a result of being advised to do so at the baseline screening assessment*</i>	14	2	12
New glasses or changed lenses recommended [‡]	24 (60%)	2 (50%)	21 (58.3%)
New glasses or changed lenses obtained [‡]	18 (45.0%)	2 (50%)	16 (44.4%)
Owned glasses at outcome assessment	40 (100%)	4 (100%)	36 (100%)
Reported regular wearing of glasses at outcome assessment	27 (67.5%)	3 (75%)	24 (60%)

* 10 people had missing data i.e. could not recall (9 in the universal and 1 in the targeted arm)

‡ 4 people had missing data (all in the universal screening arm)

Table 9.5 Uptake of optometry referrals and interventions by randomised group (for those with outcome data available)

Ophthalmology referrals

Of the 220 people eligible for referral in the universal screening arm at baseline, 65 people (29.6%) completed an outcome assessment and had data about the result of the referral available. In the targeted screening arm, of the 29 people eligible for referral, 10 (34.5%) completed an outcome assessment and had data about the result of the referral available.

The results of the referrals are shown in table 9.6.

New diagnoses and interventions

Among people who did attend, there was a range of new diagnoses and treatments for eye problems (table 9.6). Newly diagnosed cataract was much the commonest category, with the majority of those being diagnosed having had surgery, which for four people had also involved further treatment for complications. A small number of people (five) were on cataract surgery waiting lists. As described above, the outcome assessments were undertaken three to five years after the baseline screening. The five people awaiting cataract surgery had *not* been placed on waiting lists immediately following the baseline assessments. Although they had seen an ophthalmologist within one year of the baseline screen, either the diagnosis of cataract or the decision to offer them surgery had occurred between 1 and 4 years after this first appointment.

There were several new diagnoses of age related macular degeneration (AMD). There were no people for which photocoagulation therapy was recorded. Photodynamic therapy was not available in the United Kingdom during the study period. There was one recorded referral to a low vision service for a patient with newly diagnosed AMD. There were six new registrations as partially sighted or blind: five of these people had AMD and one person had glaucoma.

	All number (%)	Targeted screening group number (%)	Universal screening group number (%)
Eligible for referral	75 (100%)	10 (100%)	65 (100%)
Had ever seen an ophthalmologist (except in last 12 months)	51 (68%)	5 (50%)	46 (70.8%)
Evidence of a new referral to an ophthalmologist following the baseline assessment	41 (54.7%)	3 (30%)	38 (58.5%)
Attended an ophthalmologist following the baseline assessment	36 (48%)	1 (10%)	35 (53.8%)
<i>Action taken*</i>			
Cataract diagnosed	22 (29.3%)	1 (10%)	21 (32.3%)
Had cataract surgery	16 (21.3%)	1 (10%)	15 (23.1%)
On a waiting list for cataract surgery	5 (6.7%)	0	5 (7.73%)
Cataract diagnosed but no action taken	1 (1.3%)	0	1 (1.5%)
Diagnosis of age related macular degeneration	7 (9.3%)	1 (10%)	6 (9.2%)
Diagnosis of glaucoma	3 (4%)	0	3 (4.6%)
Glaucoma surgery or laser treatment	2 (2.7%)	0	2 (3.1%)
Medical treatment of glaucoma	3 (4%)	0	3 (4.6%)
Medical treatment other than glaucoma	7 (9.3%)	0	7 (10.8%)
Diagnosis of retinal vein occlusion	1 (1.3%)	0	1 (1.5%)
Diagnosis of refractive error	1 (1.3%)	0	1 (1.5%)
Low vision referral	1 (1.3%)	0	1 (1.5%)
Registered as partially sighted since baseline screening assessment	4 (5.3%)	0	4 (6.2%)
Registered as blind since baseline screening assessment	2 (2.6%)	0	2 (3.1%)
No new diagnoses or treatments (definite recording)	5 (6.7%)	0	5 (7.7%)

* people can be in more than category for action taken

Table 9.6 Uptake and consequences of ophthalmology referrals by randomised group for those with outcome data available (all diagnoses are newly recorded since the screening assessment)

Reasons for non-uptake of referrals or interventions

Optometry (table 9.5)

Six people who were referred to an optician did not attend (all in the universal screening arm). Of the four people who gave a reason, one said they were already under an ophthalmologist and three said they did not think they needed glasses.

Five people in the universal arm did not obtain their recommended new glasses. Of these, three people cited cost as the reason they did not obtain new glasses and two people said they did not think they needed them.

Ophthalmology (table 9.6)

Whether referrals happened

Whether people eligible for referral were actually referred was assessed from three different data sources: a tick box on the detailed baseline screening assessment forms; a search of patient medical notes for a new referral letter or evidence that they had seen an ophthalmologist since the baseline assessment; and asking the patient whether since the baseline assessment they had seen (or been invited to see) an ophthalmologist.

When a participant was found to be eligible for referral to an ophthalmologist, the screening findings and the recommendation that the patient be referred was communicated in writing by the research nurse to the general practitioner. The referral depended on the general practitioner writing a referral letter, so clearly there was scope for nurse recommendations not being translated into referrals.

There was clear evidence of a new referral for only 54.7% (41/75) of people who were eligible for referral following the baseline screening assessment. Possible explanations for this apparent under-referral are explored below.

Factors associated with referral

The proportion of people eligible for referral to an ophthalmologist for whom there was clear evidence of a new referral differed by randomised group (58.5% in the universal screening group versus 30.0% in the targeted group),

although the numbers in the targeted group were small. In the targeted group, participants who completed a detailed assessment had been selected on the basis of having a range of problems found during the brief screening assessment. As a consequence of this, the people eligible for referral to an ophthalmologist in the targeted group were more frail and more likely to have multiple problems requiring intervention than people in the universal group. These factors may explain the lower proportion eligible for referral who actually were referred.

There was marked practice variation in the proportion of people eligible for referral to an ophthalmologist for whom there was clear evidence of a new referral. In the universal screening arm, the proportion of eligible people who were referred ranged between practices from 33% to 100%. In the targeted screening arm, the numbers eligible in individual practices were very small, but again variation was seen with in one practice both eligible patients being referred and in another none of the four eligible patients being referred. Four of the practices were fundholding at the time of the baseline assessment, and there was anecdotal evidence from the research nurses that some fundholding general practitioners were concerned about the financial implications of multiple referrals arising from the multidimensional screening assessments. Excluding practices in which one or zero people were eligible for referral to an ophthalmologist, the proportion of people eligible who were referred was slightly lower in the fundholding practices (49% versus 58%). The difference was not significant ($P=0.23$) and caution is required in interpreting the difference based on such a small number of selected practices.

Characteristics of people who were referred compared with people who were not referred are shown in table 9.7.

Characteristic	All eligible for referral (n=75)	Not referred (n=34)	Referred (n=41)
Median age	81.9 years	82.5 years	81.4 years
Proportion male	25.3% (19)	26.5% (9)	26.8% (11)
Living alone	54.7% (41)	52.9% (18)	51.2% (21)
Cognitive impairment at baseline*	17.3% (13)	20.6 % (7)	12.2% (5)
Mean binocular presenting logMAR score	0.319	0.265	0.354
Mean number of referrals arising from baseline screening assessment	1.49	1.51	1.48
Previously seen an ophthalmologist	86.8% (65)	97.1% (33)	78.1% (38)

* scored less than 24 on the mini mental state examination

Table 9.7 Participants who were eligible for referral to an ophthalmologist: characteristics of people who were referred compared with people who were not referred

The age and sex distributions of those eligible who were and were not referred were similar. The proportion of people living alone was again similar among those referred and not. However, people who were not referred were more likely to have had evidence of cognitive impairment at the baseline screening assessment, indicated by a score of less than 24 on the mini mental state examination.²⁵⁹⁻²⁶¹

Previous research has identified that greater severity of the problems identified by screening²⁶² and a lower number of different recommendations for referral^{125;263} are associated with higher physician adherence to recommendations for referral arising from multidimensional screening programmes. As seen in table 9.7, people who were referred had worse vision than people who were not referred (the difference equivalent to about one line of vision on a Snellen chart), in line with previous research. However, the mean number of referrals recommended following the baseline assessment were similar for those referred and not referred.

People who were not referred were more likely to have previously seen an ophthalmologist. Data about previous eye disease was available for 58 of those people eligible for referral: 24 of those not referred and 34 of those referred. The distribution of previous diagnoses of eye disease was different for those referred and not referred. People who were not referred were more likely to have previously diagnosed age related macular degeneration (52% versus 28% for those referred) or diabetic eye disease, and less likely to have previously diagnosed cataract (22% versus 31% for those referred). The numbers of people with other diagnoses were too small to interpret meaningfully.

Uptake of referrals

Where there was evidence that a new referral had taken place, the uptake in terms of attendance was high at 87.8% overall (36 out of 41 referrals). Of the five people who did not attend, three gave a specific reason: one forgot about the appointment; one could not get to the hospital; and one did not think she needed to go.

Although the adherence by general practitioners to the recommendation for referral appears low, we do not have adequate data to be able to judge the appropriateness of the decisions to refer or not refer. Referral would have involved a clinical judgement about whether the patient would be likely to benefit from referral, and may have taken into account patient preferences. Referring someone who did not want to be referred would be a waste of time and resources as well as going against a patient's wishes. When people were referred, attendance at the clinic following referral was high. Previous studies have found rates of patient adherence to referrals arising from multidimensional assessments in the range of 46% to 76%.^{125;151;264-268} The high uptake in this trial could partly reflect appropriate selection by general practitioners of people referred. However, this is speculative and it is possible that the uptake of referrals would have been just as high among those not referred.

Effects on vision among people referred and treated

While the objective of the trial was to reduce the prevalence of visual impairment in the *population*, looking at the visual outcomes of those people eligible for referral and those who received interventions can help provide an insight into the effects of the screening intervention on vision.

Eligible for optometry referral

Among the 87 people eligible for referral to an optician following the baseline screen, 40 had an outcome assessment, shown in table 9.8. At baseline, all 40 had visual acuity of less than 6/18 in one or both eyes and there was no change in this by the time of outcome assessment (table 9.7). However, there was some improvement in the proportion of people with binocular presenting visual acuity of less than 6/18, with around a one third reduction.

The mean logMAR scores are presented for the better eye in order that the effect of pinhole correction can be assessed (binocular pinhole corrected acuity not being available). At baseline, the mean presenting best eye acuity

was substantially improved by pinhole correction, suggesting uncorrected refractive error. By the time of outcome assessment, there was little improvement in the mean presenting best eye acuity with pinhole correction, indicating a lower level of uncorrected refractive error than had been present at baseline. Thus, while there was little improvement in presenting visual acuity between baseline and outcome assessments, there was some evidence that the level of uncorrected refractive error had been reduced. The lack of improvement in presenting vision could partly be due to an overall deterioration in vision between the two assessments which were three to five years apart.

Among the 21 participants who were referred to an optician and who obtained new glasses or lenses, the mean logMAR best eye presenting vision improved from 0.373 at baseline to 0.210 at outcome (not included in the table). Particularly when considered with the likely underlying deterioration in vision with time, this indicates that vision was substantially improved when people obtained new lenses. (See appendix 12 for details of the relationship between Snellen visual acuity and logMAR scores).

	All number (%)	Targeted screening group number (%)	Universal screening group number (%)
<i>Total eligible for referral to optician following baseline screen</i>	87	8	79
Eligible for referral and outcome data available	40 (100%)	4 (100%)	36 (100%)
Visual acuity <6/18 in either eye at baseline	40 (100%)	4 (100%)	36 (100%)
Visual acuity <6/18 binocular at baseline	13 (32.5%)	0	13 (36.1%)
Visual acuity <6/18 in either eye at outcome	40 (100%)	4 (100%)	36 (100%)
Visual acuity <6/18 binocular at outcome	9 (22.5%)	1 (25%)	8 (22.2%)
<i>Continuous measure of visual acuity</i>			
Mean best eye presenting logMAR score at baseline	0.330	0.431	0.320
Mean best eye pinhole corrected logMAR score at baseline	0.219	0.300	0.210
Mean best eye presenting logMAR score at outcome	0.276	0.281	0.275
Mean best eye pinhole corrected logMAR score at outcome	0.243	0.256	0.230

Table 9.8 Vision at baseline and at outcome for people eligible for referral to an optician by randomised group (for those with outcome data available)

Eligible for ophthalmology referral

Among the 249 people eligible for referral to an ophthalmologist following the baseline screen, 75 had an outcome assessment, shown in table 9.9. At baseline, all 75 had visual acuity of less than 6/18 in one or both eyes. Again, there was no change in this by the time of outcome assessment. The prevalence of binocular presenting visual acuity of less than 6/18 was much lower at baseline, at 20% in both arms, with a slight worsening by the time of outcome assessment.

The mean presenting binocular logMAR acuity showed a small improvement of around 0.05 logMAR points. This improvement was restricted to the universal screening group, but the results for the targeted screening group were based on only ten participants.

	All number (%)	Targeted screening group number (%)	Universal screening group number (%)
<i>Total eligible for referral to ophthalmologist following baseline screen</i>	249	29	220
Eligible for referral and outcome data available	75 (100%)	10 (100%)	65 (100%)
Visual acuity <6/18 in either eye at baseline	75 (100%)	10 (100%)	65 (100%)
Visual acuity <6/18 binocular at baseline	15 (20%)	2 (20%)	13 (20%)
Visual acuity <6/18 in either eye at outcome	75 (100%)	10 (100%)	65 (100%)
Visual acuity <6/18 binocular at outcome	22 (29.3%)	4 (40%)	18 (27.7%)
<i>Missing data for visual acuity <6/18 binocular at outcome</i>	2 (2.7%)	1 (10%)	1 (1.5%)
<i>Continuous measure of visual acuity</i>			
Mean binocular presenting logMAR score at baseline	0.358	0.356	0.359
Mean binocular presenting logMAR score at outcome	0.318	0.400	0.306
<i>Missing data for logMAR binocular acuity at outcome</i>	2 (2.7%)	1 (10%)	1 (1.5%)

Table 9.9 Vision at baseline and at outcome for people eligible for referral to an ophthalmologist by randomised group (for those with outcome data available)

Effect of cataract surgery

Sixteen participants who were referred to and attended an ophthalmologist following the baseline screen had had a cataract extraction by the time of outcome assessment (table 9.6) Although all sixteen continued to have visual acuity less than 6/18 in either eye at outcome, there was an improvement in their mean presenting binocular acuity. At baseline, the mean binocular logMAR acuity for these 16 people was 0.316, and at outcome assessment it was 0.168 (a change from a Snellen equivalent of 6/12 to 6/7.5), in line with expected benefits in this age group.⁹²

Only one of the 16 people who had a cataract extraction were in the targeted screening arm, so a breakdown of these results by randomised group would not be useful. People did not have their visual function measured at baseline, meaning only changes in acuity can be assessed.

Changes in vision among people who did not have cataract surgery

There were twenty people who were referred to and attended an ophthalmologist following the baseline screen who did not have a cataract extraction by the time of outcome assessment (table 9.6) Among these people, there was no improvement in vision by the time of outcome assessment: in fact there was a slight worsening. At baseline, the mean logMAR acuity for these 20 people was 0.352, and at outcome assessment it was 0.360. Again, because participants did not have their visual function measured at baseline, only changes in acuity can be assessed.

9.3 Summary

It is unlikely that visual acuity was measured perfectly at baseline and reduced visual acuity does not accurately capture all aspects of the need for interventions to improve vision.

However, it is still likely that screening did identify a large proportion of those people who could have benefited from interventions to improve their vision. High levels of visual impairment were identified. The proportion that could be attributed to refractive error (inferred from improvement in acuity with use of a pinhole occluder) was relatively low (about 17%), but this was likely to have

been an underestimate, largely because of difficulties with using a pinhole occluder. Better methods of detecting uncorrected refractive error are needed.

Around one third of people identified as having visual impairment that could not be attributed to refractive error at baseline had seen an ophthalmologist in the previous 12 months, and a further 14% were already registered as blind or partially sighted. Overall, around one fifth of all those screened were eligible for referral to an optician or an ophthalmologist. This high proportion of people eligible for referral suggests that if recommendations for referral were taken up and effective treatments were obtained, there could have been a substantial reduction in the levels of visual impairment among people screened.

Data on the causes of non-refractive visual impairment were only available for around half those people eligible for referral. Age related macular degeneration was, as expected, common. A high proportion of people had a diagnosis of cataract, but there was some uncertainty about the proportion who had already had treatment for their cataract(s).

Only a very small proportion (2.6%) of those eligible for referral had never seen an ophthalmologist.

While a range of effective interventions for reduced vision exist, it was difficult to assess the extent to which the people identified with low vision could be expected to benefit. Clearly in order to benefit, people would first have to be referred to and attend eye services. Most people eligible for referral to an optician already attended an optician at least occasionally prior to screening and owned glasses. However, there was evidence of uncorrected refractive error suggesting their glasses were not optimal. Around one third of those eligible for referral to an optician reported that they specifically visited an optician as a result of being advised to do so after screening. By the time of outcome assessment, around half of these eligible for referral had obtained new glasses and all people who had been eligible for referral now owned glasses. Although the observed improvements in vision between the screening and outcome assessments among people referred to an optician

were modest, this must be seen in the context of their being a three to five year interval during which time some deterioration in vision may have occurred. There was evidence of a reduction in the level of uncorrected refractive error among people who obtained new lenses after screening, but the total numbers benefiting in the context of the trial were small. All data about use of optician services and glasses relied on self-report from participants and could be subject to some error in recall.

We only managed to obtain information on reasons for non-uptake of optician referrals and interventions from a relatively small number of people: too small to draw firm conclusions. However, high cost was specifically raised by half of those who gave a reason for not obtaining newly recommended glasses.

There was evidence of a new referral to an ophthalmologist for only just over half of those people eligible for a referral. This could possibly be an underestimate, for example if people were referred to an ophthalmologist without a referral letter being filed in the patient record or the letter was not extracted by the research nurse during the notes search. However, in previous trials of multidimensional screening, similarly low levels of clinician adherence to recommendations for referral have been found, with a range of 49% to 79%.^{125;265;267-270} There was a marked variation in rates of adherence to recommendations for referral between practices, with limited data to suggest that adherence was lower in fundholding practices. Possible cognitive impairment at baseline was associated with a lower likelihood of an eligible participant being referred, presumably reflecting a clinical judgement by the general practitioner about the appropriateness of the referral. People who were referred had lower visual acuity than those not referred, in line with previous work showing the severity of the problem predicted clinician adherence with a referral recommendation.²⁶² Although the data were somewhat limited, there was some evidence that people with a previous diagnosis of age related macular degeneration were less likely to be referred, while those with a previous diagnosis of cataract were more likely to be referred. This may reflect judgement by the general practitioners about the

likely benefits to the patient arising from the referral, a factor previously shown to affect clinician adherence with referral recommendations.²⁶² We were unable to assess the appropriateness of the decisions to refer.

Where there was evidence of a new referral to an ophthalmologist, attendance rates at the clinics were high at 87.8%. Previous studies have found rates of patient adherence to referrals arising from multidimensional assessments in the range of 46% to 76%.^{125;151;264-268} Although none of the previously reported rates for uptake of referrals by patients were specifically derived from ophthalmology referrals, the rate in this trial was noticeably high. A variety of new diagnoses were made among those people who attended and a number of different interventions occurred. Much the commonest intervention was cataract extraction. The total number of people referred who subsequently had a cataract extraction was small at 16, but their vision improved. However, for the remaining people who attended their ophthalmology referral, there was no improvement in visual acuity from baseline. It is possible that some of these people may have benefited from rehabilitation or other measures that improved their visual function without improving measured visual acuity. However, because visual function was not assessed at baseline, we could not assess this.

About half the people referred to an optician obtained new lenses, their level of uncorrected refractive error was reduced and their presenting vision improved. Similarly, around half the people referred to an ophthalmologist had cataract surgery and their vision improved. However, in the context of the trial population, the numbers of people benefiting were small. These findings are consistent with the findings in the whole population screened, among whom little or no improvement in vision overall was seen due to screening.

CHAPTER 10. DISCUSSION AND CONCLUSIONS

10.1 Discussion

Introduction

The systematic review of randomised trials (Chapter 2) showed there was no evidence for the effectiveness of screening older people for visual impairment.^{271;272} Factors common to all the existing trials were identified that could have contributed to the observed lack of effectiveness:

- lack of a clear plan of intervention for those people found to have visual impairment;
- the use of single questions about visual difficulties as both the screening tool and to assess outcome;
- the fact that visual function was not measured at outcome.

Visual outcomes were therefore assessed in a larger trial of multidimensional assessment of older people in a nested trial design that overcame the possible drawbacks identified in the previous trials. The new trial again found no evidence for the effectiveness of screening for visual impairment, although a small beneficial effect could not be excluded. In Chapter 9, a range of process measures were considered as possible explanations for the effect observed in the trial. In this chapter, aspects of the trial design and execution are considered and the implications for practice, policy and research considered.

The screening interventions compared

This trial was not a straightforward comparison of screening versus no screening. At the time the trial was started, there was a contractual obligation on primary care teams to offer an annual screening assessment to all patients aged 75 and over (the “over 75s check”), specifically including an assessment of vision.²² It was therefore not possible to have a “no screening” control arm in the trial. The screening intervention in the targeted intervention group of the MRC trial of the assessment and management of older people in

the community was designed to be the minimal screening assessment that covered all areas specified for the over 75s check in the general practice contract. The targeted screening arm acted as the comparison group for the purposes of the nested vision screening trial.

Targeted screening group

In the targeted arm, all participants were asked about visual problems as part of a brief assessment. Criteria for then being offered a more detailed assessment (that included a visual acuity screen) were three or more problems identified from the brief assessment or any one of four "serious" symptoms (unexpected weight loss, frequent falls in previous month, vomiting blood, coughing blood). Among the 1684 participants in the targeted screening arm of the nested vision screening trial who completed a brief assessment, 150 (8.6%) reported sufficient problems to be eligible for a detailed assessment, and 120 attended (see Chapter 6, especially figure 6.1 and table 6.6). A total of 29 people in the targeted arm were eligible for referral to an ophthalmologist, and a further eight people were eligible for referral to an optician. Therefore a total of 2.2% (37/1684) were eligible for referral to the eye services.

Universal screening arm

In the universal screening arm, all participants were offered both brief and detailed assessments. 220 people were eligible for referral to an ophthalmologist, and a further 79 people were eligible for referral to an optician. Therefore a total of 18.0% (299/1662) of participants in the universal screening group were eligible for referral to the eye services.

Possible effects on the trial result

If referral to the eye services had a large impact on improving vision, there could have been a improvement in the prevalence of visual problems in the targeted screening group (which was effectively the control comparison group in the trial) and hence an under-estimation of the effectiveness of screening in the trial. However, given the very small proportion of people eligible for referral in the targeted group (2.2% compared with 18.0% in the universal screening group), even if referral had had a dramatic effect on

vision, there would have been little impact on the overall prevalence of visual problems in the targeted group and thus little impact on the trial result.

In fact, as seen in Chapter 9, even among those people eligible for referral to the eye services following screening, the improvements in vision were modest overall.

In summary, although a small number of people in the comparison or control arm of the trial did have a visual screen, this was unlikely to have had a substantial effect on the estimate of effectiveness of screening from the trial.

Trial outcomes

Visual acuity

Measurement error

As described in Chapter 9 in the context of visual acuity testing at the screening assessment, there was likely to be some measurement error in the visual acuity outcome measurements. However, for the outcome assessments, the research nurses received a full day training focused entirely on vision. In addition the design of the data collection form (appendix 8) helped reduce the possibility of invalid values for visual acuity being entered. The numbers of missing, implausible and inconsistent values were very low indeed.

As with the baseline screening assessments, the research nurses were asked to take steps to ensure adequate lighting. Just over half the outcome assessments were undertaken in peoples' homes where lighting levels are likely to have been more variable than in the clinic setting.⁶⁴ However, the proportion of people who had their vision measured at home was similar in the two arms of the trial. The use of a one metre testing distance because of space restrictions was low at 6.2%, and again the proportion was similar in the two arms of the trial.

Overall, although there was likely to have been some measurement error, it seems unlikely that error in the visual acuity outcome assessments could have affected the results of the trial substantially.

One or both eyes

The primary acuity outcome measure was visual acuity less than 6/18 in *either* eye, with binocular presenting acuity as a secondary outcome measure. The main reason for this choice was that it directly measured the intervention. Eligibility for referral to eye services was based on reduced visual acuity in either eye, not on binocular or better eye acuity.

In developed countries, interventions (such as cataract extraction) are undertaken on the basis of reduced acuity in one eye, even if the acuity is relatively good in the other eye. This is justified because there is evidence that second eye surgery for cataract (after successful surgery for cataract in the first eye) produces similar gains in terms of visual function as first eye surgery.^{273;274} In contrast to this finding, it has been shown that acuity in the better eye is a good predictor of binocular acuity, and certainly a much better predictor than acuity in the worse eye.²⁷⁵ Rubin et al suggest that this apparent contradiction may be explained by second eye surgery having a beneficial effect on measures such as reading speed, mobility and self perceived visual disability,^{276;277} even though it has relatively little effect on binocular acuity.

Visual function

As previously discussed in Chapters 1 and 3, visual acuity is not the only factor that influences a person's visual function. Visual field loss, reduced contrast sensitivity, glare, reduced stereoacuity and poor home lighting can have an adverse effect on vision, even though on formal testing visual acuity may be preserved. Rather than attempting to undertake a complex battery of objective ophthalmological measures, and also because in recent years the value of visual function indices in assessing the effectiveness of interventions to improve vision has become widely accepted, we assessed visual function as a subjective measure of how visual problems (of whatever sort) affected peoples' ability to function in an everyday setting.⁸⁵

Choice of visual function scale

At the time we designed the outcome data collection, the National Eye Institute Visual Function Questionnaire was emerging as a leading research tool for assessing visual function, in part because of its promotion by the National Eye Institute. The shortened 25 item version was developed to measure the dimensions of self-reported vision related health status that are of greatest importance to people with chronic eye disease and to be quicker and easier to administer. The main reason for choosing this particular tool was that it was specifically developed to be able to assess people with a broad spectrum of eye diseases and vision impairments. In addition, the NEI VFQ includes an assessment of the psychological and emotional impact of reduced vision. Although the NEI VFQ had been little used in the United Kingdom, in the pilot study there were no problems with its use when compared to the VF-14 scale which had been extensively used in the United Kingdom. The VF-14 was initially developed specifically in the context of cataract. The NEI VFQ was therefore chosen given its development among people with a broader spectrum of causes of reduced vision.

A generic vision-related quality of life questionnaire called the VCMI has been developed in the United Kingdom.¹⁸⁵ The initial validation study of the final version was undertaken in 92 people and suggested the VCMI was a promising instrument. However, at the time we were designing the outcome assessments for the vision screening trial, the VCMI had only just been published and, particularly among very elderly people, there was no experience of its use outside of the validation work undertaken by the developers.

The trial result for the NEI VFQ composite score was consistent with the visual acuity results. In this trial, the correlation coefficient for the composite NEI VFQ-25 score and the presenting binocular logMAR visual acuity was – 0.53 (the negative simply a function of the fact that better visual acuity produces a lower logMAR score). The correlation coefficient for the composite NEI VFQ-25 score and the presenting best eye logMAR visual acuity was -0.50 and for the presenting worst eye was -0.44. These

correlation coefficients are somewhat lower than those recorded by Mangione et al in a North American population: -0.72 for the better eye and -0.69 for the worst eye.²⁰³ The figures from North America are derived from a specially assembled test sample of 598 people.¹⁸³ This sample was a mixture of 476 people with reduced vision due to a single eye disease and 122 people with no eye known eye disease (except possible refractive error). The age of the sample varied by diagnostic category, but overall was considerably younger than the participants included in this trial. Differences in results for the North American sample and this trial population could therefore be expected. However, the differences in the correlation coefficients are not large enough to suggest that the NEI VFQ-25 is less valid among a United Kingdom population.

A problem with the 25 item NEI VFQ evident in this trial was a ceiling effect, whereby the majority of participants obtained very high scores. The median score was 93.4, and the 25th centile was 82.9. This ceiling effect means that the NEI VFQ may be insensitive to small differences in visual function among people with quite high levels of visual function.

NEI VFQ-25 subscales

The longer 51 item NEI VFQ is divided into 13 sub-scales. However, factor analysis of the NEI VFQ-51 suggests that it measures only four different domains: general health, ocular pain, vision expectations and daily functioning.⁸⁵ In reducing the 51 item scale to 25 items, all the vision expectation questions were dropped. This suggests that the NEI VFQ-25 measures three domains only.

The low number of items in most of the sub-scales, the large number of sub-scales (and therefore comparisons), the possible impact of missing values, and the suggestion that in fact only three domains are measured by the various sub-scales, all mean that great caution is required in the interpretation of the sub-scale results. In fact in this trial, the sub-scale results were all consistent with the visual acuity and VFQ composite score results.

Overall it can be concluded that while there were some imperfections in the outcomes measured in the trial, the outcome data were likely to have been adequate to assess whether the vision screening intervention had a beneficial effect on vision.

Time period and attrition between screening and outcome assessment

Time period

As seen in Chapter 7, the time period between screening and outcome assessment was quite long, with a median of 3.9 years. It is possible that improvements in vision occurring soon after screening could have been missed, with progressive disease or new eye problems cancelling out these earlier gains during the extended follow-up. However, as seen in table 7.5, a substantial proportion of participants were assessed between 1.6 and 3 years after baseline screening, and the intervention did not appear to be more effective in this sub-group. In fact, the effectiveness of the screening intervention on vision did not vary by period of follow-up at all (table 7.8).

Therefore although the follow-up period was relatively long for many participants, it did not appear to have a major effect on the effectiveness of screening.

Attrition

The response rates and reasons for non-response by randomised group were presented in table 7.1. As discussed in detail in Chapter 7, the apparently low response rate to the outcome assessments was largely due to the high mortality rate of people in this age group and the relatively long follow-up period. The death rates were very similar in the two arms. The possible effect of mortality on the trial outcomes is considered below.

Excluding people who had died, the response rate was 62.8%, which for a trial in this age group is comparatively high. Only 28% of people who could have completed an outcome assessment (i.e. were alive and were not too ill, in hospital or had moved away) refused or did not respond, meaning that 72% of people who *could* have been seen by the study nurses did have an

outcome assessment. However, there was some imbalance in response rate by randomised group. Overall there was a 5.7% difference between the two groups, with a lower response rate in the universal screening group. The possible effects of this differential in response rate across the two groups was considered in some detail in Chapter 7. To have affected the trial results, non-response would need to have been associated with vision. Among people who completed baseline screening, non-response to the outcome assessment was not associated with vision. Although there is no clear evidence to suggest that the difference in response rate to the outcome assessments in the two arms led to bias in the result, a small effect cannot be entirely excluded.

Effect of mortality on outcomes

Just over one third of participants had died by the time of outcome assessment (shown in table 7.1), with the proportions being very similar in the two arms of the trial. It is possible that some people could have been referred to the eye services and obtained help with their vision following the screening assessment, but died prior to having an outcome assessment. This could have reduced the observed effectiveness of screening. While we cannot know the visual outcomes following screening for those people who had died, we can gain some impression of the possible effect of mortality on the trial outcomes.

Firstly, if mortality did affect the outcome, it would be expected that the trial outcome would differ by period of follow-up, with more people dying as the follow-up period increased. However, as seen in table 7.8, the effectiveness of the screening intervention on vision did not vary at all by period of follow-up. Secondly, we can undertake a sensitivity analysis to assess the effect of mortality if we assume that the visual outcomes of people who died were the same as people who did not die. That is, for people who were not referred to the eye services but who died, we assume their vision followed the pattern of people who were not referred to the eye services and did *not* die. Similarly, we assume that for people who *were* referred to the eye services but who died, their vision followed the pattern of people who were referred to the eye

services and did *not* die. This assumption may be over-optimistic, because people who died within 1.6 to 5 years of screening may well have been more frail and have had less improvements in vision than people who did not die. However, although it may be over-optimistic, this assumption is still useful for a sensitivity analysis. Imputing the visual acuity results as described, the odds ratio of having impaired vision (defined as visual acuity $<6/18$ in one or both eyes) comparing the universal screening group with the targeted screening group was 1.17, 95% confidence interval 0.86 to 1.57. $P=0.49$. This is almost identical to the main trial result observed (odds ratio 1.11), further suggesting that the high mortality rate had little effect on the effectiveness estimate.

Other trial factors possibly affecting the results

Confounding

The randomised design of the trial reduced the scope for confounding. However, in spite of the large number of participants, the cluster randomisation meant that confounding could still have been an issue because of variation between practices and the fact that there were effectively only 10 randomised units in each arm.

As seen in Chapter 6, the randomised groups were well balanced at both practice and individual level. Also as seen in Chapters 7 and 8, the inclusion of a range of potential confounding factors in the outcome models had no appreciable impact on the estimate of effectiveness.

Bias

Randomisation procedure and allocation concealment

Randomisation procedure and allocation concealment are rightly seen as critical issues in randomised trials of individuals.^{133;179} Like most cluster trials, the way that randomisation was executed in this trial meant that allocation was effectively concealed. Practices agreed to participate in the trial before they were randomised, and because of this time sequence and because randomisation was done centrally by computer, neither the practice nor the

trial co-ordinators could know which arm of the trial a practice would be randomised to.

The baseline interventions were carried out as part of the routine “over 75 health checks” in the trial practices. Participants would have been very unlikely to know the details of the differences between the two interventions being tested.

Contamination

The scope for contamination (i.e. people in the targeted screening arm having a detailed assessment even though they were not eligible or vice versa) was greatly reduced by the cluster design. In the targeted arm, all 120 people who had a detailed assessment met the eligibility criteria for a detailed assessment. In the universal screening arm, 132 people who completed a brief assessment did not have a detailed assessment. The reasons for this attrition are given in figure 6.1. A further 35 people had a detailed assessment without having completed a brief assessment, but this would not be expected to have an effect on the result of screening.

The low level of contamination is reflected in the per-protocol results for the trial, which are virtually identical to the intention to treat results (Chapters 7 and 8).

Blinding of outcome assessments

Blinding of outcome assessment is known to affect the results of randomised trials.¹³³ In this trial, the research nurses were aware of whether the practice they worked in had been randomised to the targeted or universal screening arm. Some of the research nurses who carried out the outcome assessments were the same nurses who carried out the baseline screening assessments. However, the cluster design meant that nurses were undertaking outcome assessments on participants in one arm of the trial only, making such blinding almost an irrelevance. For example, all the participants assessed by a nurse in one of the practices allocated to universal screening would have been offered the same detailed assessment. Knowledge of the intervention

the practice had been allocated to would therefore be unlikely to have an impact on the outcome assessments.

Power

Outcome data were available for 1807 people, 90.4% of the target of 2000 derived from the power calculation. Thus the trial had slightly lower power than we had planned. The confidence intervals for the primary outcome measures provide a good indication of the degree of random error around the results.

The odds ratio for the primary visual acuity outcome measure as was 1.11, with a 95% confidence interval of 0.76 to 1.62, $P=0.58$. To help interpretation, the result can be expressed as a relative risk, allowing the percentage change in the outcome to be assessed. The relative risk was 1.08, 95% confidence interval 0.85 to 1.37. The lower level of the 95% confidence interval for the primary visual acuity outcome indicates that a small beneficial effect (of around a 15% reduction in visual impairment) cannot be excluded. However it is of course unlikely that the “true” estimate of the effect would be towards one extreme of the confidence interval.

For the NEI VFQ-25 composite score, the difference between the two groups was 0.41, with a 95% confidence interval -1.68 to 2.50, $P=0.69$. Even if the “true” effect were the upper level of the confidence interval, an improvement of 2.50 in the composite VFQ-25 score would represent only a very small overall benefit.

Explanations for the lack of effect observed

Complex intervention trials

In recent years there has been increasing recognition of the need to explore in detail explanations for the effect or lack of effect observed in complex intervention trials.²⁷⁸ With regards to health promotion interventions in primary care, the need to clarify the theoretical basis for the intervention and specify and assess process measures was identified in the MRC Topic

Review of Primary Health Care.²¹ These ideas have recently been developed into a three part framework for considering complex interventions:²⁷⁹

- the evidence and theory that informs the intervention ;
- the implementation of essential processes;
- the context within which the intervention will be operationalised.

With regards to this trial, some elements of this approach were successfully completed. The detailed literature review (Chapter 1) broke the complex intervention of screening older people for impaired vision down into different stages, each of which contributes to the effectiveness of the intervention. The systematic review of existing trials identified possible explanations for the lack of effect previously observed and informed the design of the new trial. However, although attempts were made to measure process variables during the trial, the research resources available were limited. The main focus of effort was obtaining sufficient data to be able to answer the primary objectives of the trial: assessing the overall effectiveness of testing visual acuity as part of a multidimensional screening assessment. The primary research objective was met, but at a cost to the secondary objective of identifying barriers to improving vision among older people.

Explanatory factors

These were considered in detail in Chapter 9 and only a few key points are summarised and briefly discussed here.

High levels of visual impairment were found among participants: almost 29% had a visual acuity less than 6/18 in either eye. In spite of a high level of glasses ownership, 17.5% people with visual impairment had evidence of uncorrected refractive error. The level of uncorrected refractive error would have been under-estimated because many eligible people did not complete a pinhole assessment.

probably under-estimated, largely because of difficulties using a pinhole occluder in this age group. Among people in whom refractive error was

diagnosed, around half obtained new glasses and the level of uncorrected refractive error was reduced.

For people with visual impairment *not* thought to be due to refractive error, 35% had seen an ophthalmologist in the past 12 months and a further 14% were registered blind or partially sighted. Both these groups were not eligible for referral. Only around half of those people recommended for referral to an ophthalmologist were actually referred, although when referral did occur, attendance at eye clinics was high. People with worse vision were more likely to be referred and people with evidence of cognitive impairment at the time of screening were less likely to be referred. However, explanations for the low adherence by general practitioners to recommendations for referral are lacking.

Around half of those who attended an ophthalmologist following screening had cataract surgery and their vision improved. Among the remaining people who attended an ophthalmologist following screening, there was no improvement in visual acuity. It is possible that some of these people received interventions for low vision that were of benefit in terms of function and quality of life, but that would not be expected to improve visual acuity.¹⁰⁴ We did not measure visual function at baseline so cannot assess changes by the time of outcome assessment. A recent review and a subsequent postal survey of low vision services in the United Kingdom found inadequacies of service provision in their distribution and comprehensiveness.^{280;281} It is therefore likely that while some people identified at screening as being visually impaired may have benefited from low vision services, others would not have been offered the full range of services from which they could have benefited.

Pragmatic nature of the trial

This was a pragmatic trial designed to assess the effect of a policy decision to include a visual acuity component in a multidimensional screening assessment for older people. The possible problems observed such as the low completion rate for the pinhole assessment and the low referral rate by

general practitioners, are components of the effectiveness of the intervention in everyday practice. Although such problems could have been overcome through rigorous adherence to a study protocol by highly motivated and trained clinicians, this would actually provide a less useful measure of the effectiveness of the intervention in everyday practice. The trial was carried out to a large extent within the context in which the intervention, if introduced, would be operationalised.

The trial findings in the context of the previous trials

From the systematic review of the five previous trials of screening older people for visual impairment using self reported measures of visual problems for both the baseline screen and the outcome assessment, the pooled odds ratio for visual problems at outcome was 1.04 (95% confidence interval 0.89 to 1.22, $P=0.63$). In the new trial, the odds ratio of having impaired vision (defined as visual acuity $<6/18$ in one or both eyes) was 1.11, 95% confidence interval 0.76 to 1.62, $P=0.58$ (table 7.6). The results for the visual function composite score were very similar – virtually no difference between the groups (difference in score 0.41, 95% confidence interval -1.68 to 2.50, $P=0.69$). Overcoming the possible problems identified with the existing trials included in the meta-analysis did *not* lead to a different estimate of the effect of screening, suggesting that these problems were not the explanation for the lack of effectiveness of screening.

Because of the cluster design of the new trial and because of a difference in the interventions being assessed in the new trial and the five previous trials, it is not appropriate to incorporate the results of this trial in the existing meta-analysis.²⁸²

10.2 Implications for practice and policy

The aim of population screening of older people for visual impairment is to discover visual impairment in those who are not presenting to the health services, and to offer them interventions to improve their vision. The

evidence from randomised controlled trials undertaken to date does not currently support the inclusion of a visual component in multidimensional screening programmes for older people in a community setting. Vision is specifically listed as a domain to be included in the Single Assessment Process to be offered to all older people proposed in the National Service Framework for Older People.²⁷ The most recently issued guidance about the Single Assessment Process recommends the inclusion of two questions about self-perceived visual problems.²⁸ However, the evidence to date does not support either the inclusion of questions about vision nor visual acuity testing.

There was evidence that uncorrected refractive error found at screening was improved by people attending opticians and obtaining new lenses. It is likely that uncorrected refractive error is under-detected among older people, and the levels detected in this study were almost certainly an under-estimate. Better detection and management of uncorrected refractive error offers scope to improve vision among this age group. However neither nurses nor doctors in general practice are trained to accurately assess refractive error, and general practices also lack the equipment required. In addition, it is unlikely that an adequate assessment of refractive error could be undertaken in the context of a multidimensional screening assessment in which vision is only one of many domains being assessed.

The use of optometry services to identify visual problems among the older population may provide scope for better detection and management of refractive error. The re-introduction of free sight tests for older people has removed one barrier to optician services. Opticians are also better placed to measure other visual factors such as visual fields or contrast sensitivity that can have an impact on peoples' lives. If opticians were able to refer directly to ophthalmology services, the problems of under-referral for non-refractive error related visual impairment could probably be overcome. However, at present in the United Kingdom the screening role for opticians is limited to glaucoma screening for people at high risk, and, in some areas, screening people with diabetes for retinopathy. The extent to which opticians are integrated into local health systems varies. Developing a closer working

relationship with opticians offers a possible way forward for Primary Care Organisations trying to reduce visual problems among older people.

Identifying problems that warrant referral to specialist services is a central aim of multidimensional screening for older people. A key finding in this trial was that only around half of those people for whom referral to an ophthalmologist was recommended were actually referred. The explanation for this low rate of adherence was not clear, nor whether the decisions to refer or not were appropriate. However there are good grounds for measuring clinician adherence to recommendations for referral in future programmes of multidimensional screening for older people, including an assessment of the appropriateness of the referral decision and the extent to which the patient was involved in the decision. Previous work has shown that when participants in multidimensional screening programmes are advised about the need for referral and the participants themselves see the doctor and request the referral, there is an 11 fold increase in doctor adherence to the referral recommendation.²⁶⁷ Patient empowerment may therefore be an effective method of improving clinician adherence to recommendations for referral.

10.3 Implications for research

Further work is clearly required to identify effective strategies to detect and improve visual problems among older people.

There are a number of unresolved issues around optimal tools to be used for screening for visual impairment, particularly in the context of multidimensional screening in primary care. If primary care teams are to be expected to detect refractive error, better methods of diagnosis which can be completed by a higher proportion of the older population than the pinhole assessment will be needed. Whether visual acuity is a good screening tool to identify people who are likely to benefit from interventions to improve their vision needs to be assessed. The value of screening for other measures such as visual fields or contrast sensitivity warrants further work. While single questions about self-reported visual difficulties are poor predictors of low

visual acuity, the development of brief screening instruments that assess visual function could be of great value.

With regards to multidimensional assessment for older people, a notable feature of this trial was the low level of ophthalmological referrals for those people deemed eligible for referral following screening. There has been some previous research on this issue (described in Chapter 9), but this has not focused specifically on eye referrals. There is scope for more research on the determinants of clinician adherence to recommendations for referrals arising from multidimensional assessments. Specific issues of interest are assessing the appropriateness of the referral decisions made and the role of the patient in the decision whether to refer or not.

The effectiveness of an increased role for optometry services in the detection and management of visual problems among older people on a population basis warrants evaluation.

Although attempts were made in this trial to examine and explore process measures, this was not the primary aim of the trial and the data available were limited in both amount and depth. Detailed prospective research on the detection, referral, diagnosis, and management of visual problems in older people could help shed further light on the reasons for the ineffectiveness of screening and offer more pointers for further research. As well as looking at health service issues, research from the perspective of the older people themselves is also needed. Areas which particularly need to be addressed include: older peoples' perceptions of their visual problems and of the need for interventions; and perceived barriers to interventions to help their vision. Clearly much of this research would need to be qualitative in nature.

10.4 Summary of findings

- A systematic review of randomised trials found no evidence to support the inclusion of a visual component in multidimensional screening programmes for older people. However, the existing trials used questions about self-reported visual difficulties as a screening tool and to assess

outcome; lacked a clear plan of intervention for those people found to have visual impairment; and did not measure visual function as an outcome.

- The present trial was nested within a larger cluster randomised trial of multidimensional screening for people aged 75 years and over. General practices were randomised to a targeted screening strategy in which only a small proportion of participants with a range of health problems were offered visual acuity screening or to a universal screening strategy in which all participants were offered visual acuity screening. Around 220 eligible participants were randomly sampled from ten practices in each arm of the trial and visual acuity and visual function were measured three to five years after the screening intervention.
- The response rate to the baseline assessments was around 76%.
- A high level of visual impairment was found: almost 29% of people had visual acuity of less than 6/18 in either eye.
- Among people with visual impairment, 17.5% could be attributed to refractive error. Uncorrected refractive error was under-detected because the pinhole assessment was completed by a minority of participants.
- Of the remaining people with visual impairment, 35% had seen an ophthalmologist in the previous year and a further 14% were registered blind or partially sighted.
- Over one third of eligible participants died before having an outcome assessment. Of those alive, the response rate to the outcome assessment was 67.8% in the targeted group and 57.9% in the universal group.
- Around half the people referred to an optician had obtained new lenses and their level of uncorrected refractive error improved.
- Only 52% of the people recommended for referral to an ophthalmologist had been referred by their general practitioner: among those referred the attendance rate was over 80%.

- Among people who attended an ophthalmology clinic following referral, around half had a cataract extraction and their vision improved. However, there was no improvement in visual acuity for the remaining half who did not have a cataract extraction.
- Three to five years after the initial screening intervention, 37.0% (307/829) of people in the universal group had visual acuity of less than 6/18 in either eye compared with 34.7% (339/978) of people in the targeted group (odds ratio 1.11, 95% confidence interval 0.76 to 1.62, $P=0.58$). The composite score of the 25 item National Eye Institute Visual Function Questionnaire (maximum score 100, higher scores indicate better function) was 86.03 in the universal group and 85.62 in the targeted group, a slightly better score (difference 0.41, 95% confidence interval -1.68 to 2.50, $P=0.69$).
- Possible factors contributing to the observed lack of benefit include:
 - only around half those recommended for referral to an ophthalmologist were referred;
 - under-detection of uncorrected refractive error;
 - differential response rate to the outcome assessment between the two randomised groups;
 - inadequacies in the outcome measures used to assess benefits;
 - the intervention and visual acuity outcome focused on the worse eye rather than on peoples' vision;
 - the intervention was not optimised prior to implementation;
 - chance.

10.5 Summary of recommendations

- Visual impairment is common and disabling among older people and there is potential to improve the vision of people in this age group.
- The evidence from randomised controlled trials undertaken to date do not support the inclusion of a visual screening component in multidimensional screening programmes for older people in a community setting.
- The recommendation that an assessment of vision be included in the Single Assessment Process proposed in the National Service Framework for Older People is not supported by the evidence.
- The effectiveness of an optimised primary care based screening intervention that overcomes possible factors contributing to the observed lack of benefit in trials to date needs to be assessed.
- Specific issues to be addressed include:
 - the appropriateness of visual acuity as a screening tool for primary care to identify those people who can benefit from visual interventions;
 - whether use of the pinhole occluder in primary care can be improved through training or whether alternative strategies to detect uncorrected refractive error are needed;
 - assessing the benefits of referral to an ophthalmologist for older people with reduced vision that is not due to cataracts;
 - identification of factors influencing clinician and patient adherence to recommendations for referral arising from multidimensional assessments and the appropriateness of these referrals;
 - outcome measures that are better able to assess the benefits of screening;
 - the effectiveness of an increased role for optician services in the detection and management of visual problems among older people.

- Complex intervention trials should include a substantial element of research that examines process measures and aims to explain the reasons for the effectiveness observed in the trial.
- Given the importance of visual impairment among older people, further research into strategies to improve vision of older people is warranted.

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APPENDICES

Appendix 1 Search strategies used for the systematic review of randomised trials

Appendix 2 Data extraction sheets for the systematic review of randomised trials

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Appendix 1

Search strategies used for the systematic review of randomised trials

The following strategy was used to search CENTRAL Issue 1 2002:

- #1 VISION-SCREENING:ME
- #2 MULTIPHASIC-SCREENING:ME
- #3 MASS-SCREENING:ME
- #4 PREVENTIVE-HEALTH-SERVICES:ME
- #5 DIAGNOSTIC-SERVICES:ME
- #6 (screen*)
- #7 (((((#1 or #2) or #3) or #4) or #5) or #6)
- #8 AGED*:ME
- #9 (((geriatric* or elder*) or "older people") or senior*)
- #10 (#8 or #9)
- #11 (#7 and #10)
- #12 GERIATRIC-ASSESSMENT:ME
- #13 HEALTH-SERVICES-FOR-THE-AGED:ME
- #14 ((#11 or #12) or #13)

The following strategy was used to search MEDLINE up to March 2002:

- #1 "MULTIPHASIC-SCREENING"/ all subheadings
- #2 "MASS-SCREENING"/ all subheadings
- #3 "DIAGNOSTIC-SERVICES"/ all subheadings
- #4 screen* or assessment or surveill*
- #5 (#4 in TI) or (#4 in AB)
- #6 #1 or #2 or #3 or #5
- #7 explode "AGED"/ all subheadings
- #8 (geriatric or elder* or older people or senior*)
- #9 (#8 in TI) or (#8 in AB)
- #10 #7 or #9
- #11 "GERIATRIC-ASSESSMENT"/ all subheadings
- #12 "HEALTH-SERVICES-FOR-THE-AGED"/ all subheadings
- #13 #11 or #12
- #14 "VISION-SCREENING"/ all subheadings
- #15 explode "EYE-DISEASES"/ all subheadings
- #16 eye* or vision or visual or macular degeneration* or cataract* or presbyopia
- #17 (#16 in TI) or (#16 in AB)
- #18 #15 or #17
- #19 #6 and #10 and #18
- #20 #13 and #18
- #21 #10 and #14
- #22 #19 or #20 or #21

To identify randomised controlled trials, this search was combined with the Cochrane Highly Sensitive Search Strategy phases one and two as contained in the Cochrane Reviewer's Handbook.

The following strategy was used to search EMBASE up to March 2002.

- #1 "SCREENING"/ all subheadings
- #2 "MASS-SCREENING"/ all subheadings
- #3 "PREVENTIVE-HEALTH-SERVICE"/ all subheadings
- #4 (screen* or assess* or surveill*)
- #5 (#4 in TI) or (#4 in AB)
- #6 #1 or #2 or #3 or #5
- #7 "AGED"/ all subheadings
- #8 (geriatric or elderly or older people or senior*)
- #9 (#8 in TI) or (#8 in AB)
- #10 #7 or #9

#11 explode "EYE-DISEASE"/ all subheadings
#12 eye* or vision or visual or macular degeneration* or cataract* or
presbyopi*
#13 (#12 in TI) or (#12 in AB)
#14 #10 or #13
#15 explode "VISION-TEST"/ all subheadings
#16 #6 and #10 and #14
#17 #10 and #15

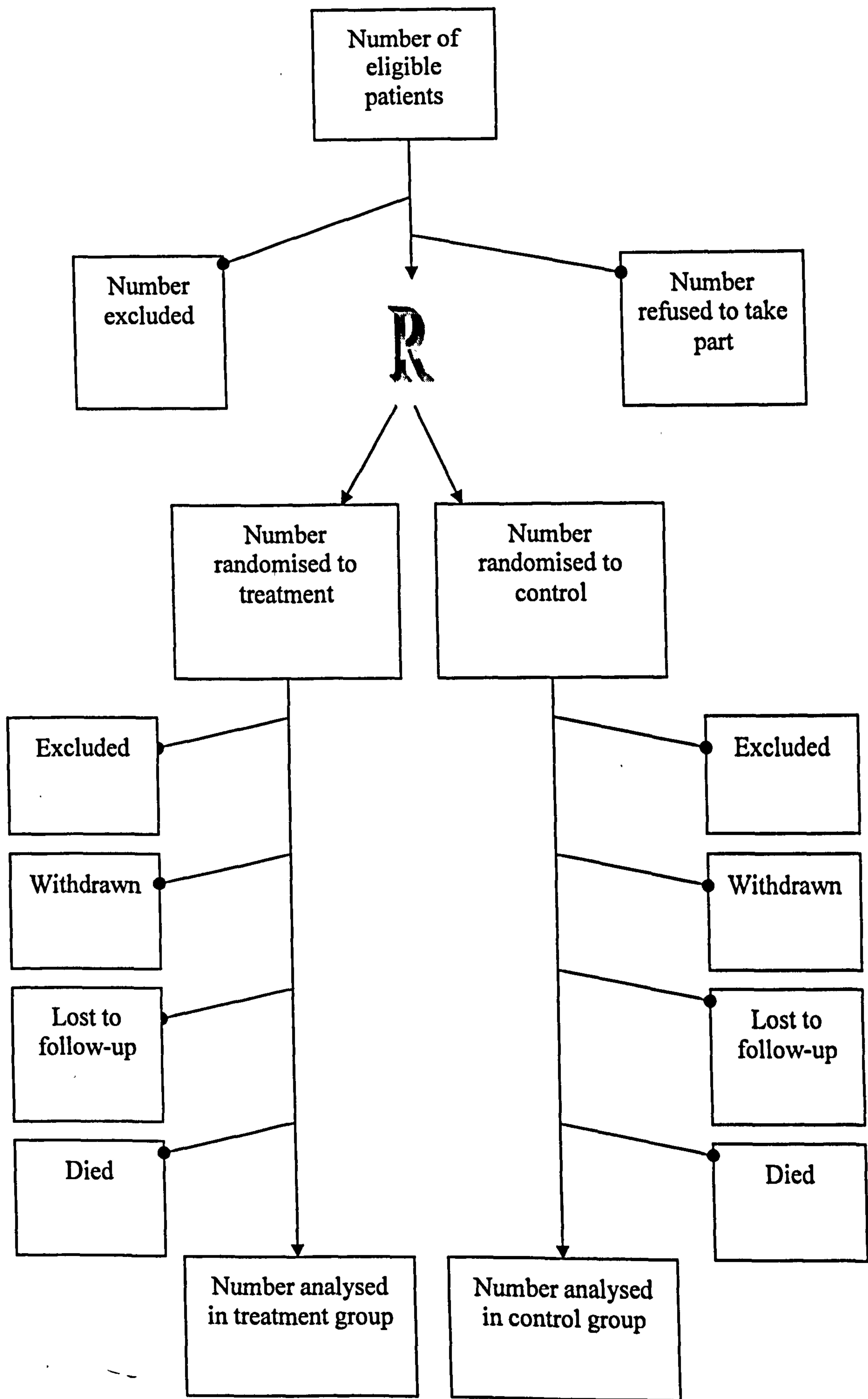
To identify randomised controlled trials, this search was combined with
the following search:

#1 "RANDOMIZED-CONTROLLED-TRIAL"/ all subheadings
#2 "RANDOMIZATION"/ all subheadings
#3 "CONTROLLED-STUDY"/ all subheadings
#4 "MULTICENTER-STUDY"/ all subheadings
#5 "PHASE-3-CLINICAL-TRIAL"/ all subheadings
#6 "PHASE-4-CLINICAL-TRIAL"/ all subheadings
#7 "DOUBLE-BLIND-PROCEDURE"/ all subheadings
#8 "SINGLE-BLIND-PROCEDURE"/ all subheadings
#9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10 RANDOM* or CROSS?OVER* or FACTORIAL* or PLACEBO* or VOLUNTEER* in
TI,AB
#11 (SINGL* or DOUBL* or TREBL* or TRIPL*) near (BLIND* or MASK*) in
TI,AB
#12 #9 or #10 or #11
#13 HUMAN in DE
#14 (ANIMAL or NONHUMAN) in DE
#15 #13 and #14
#16 #14 not #15
#17 #12 not #16

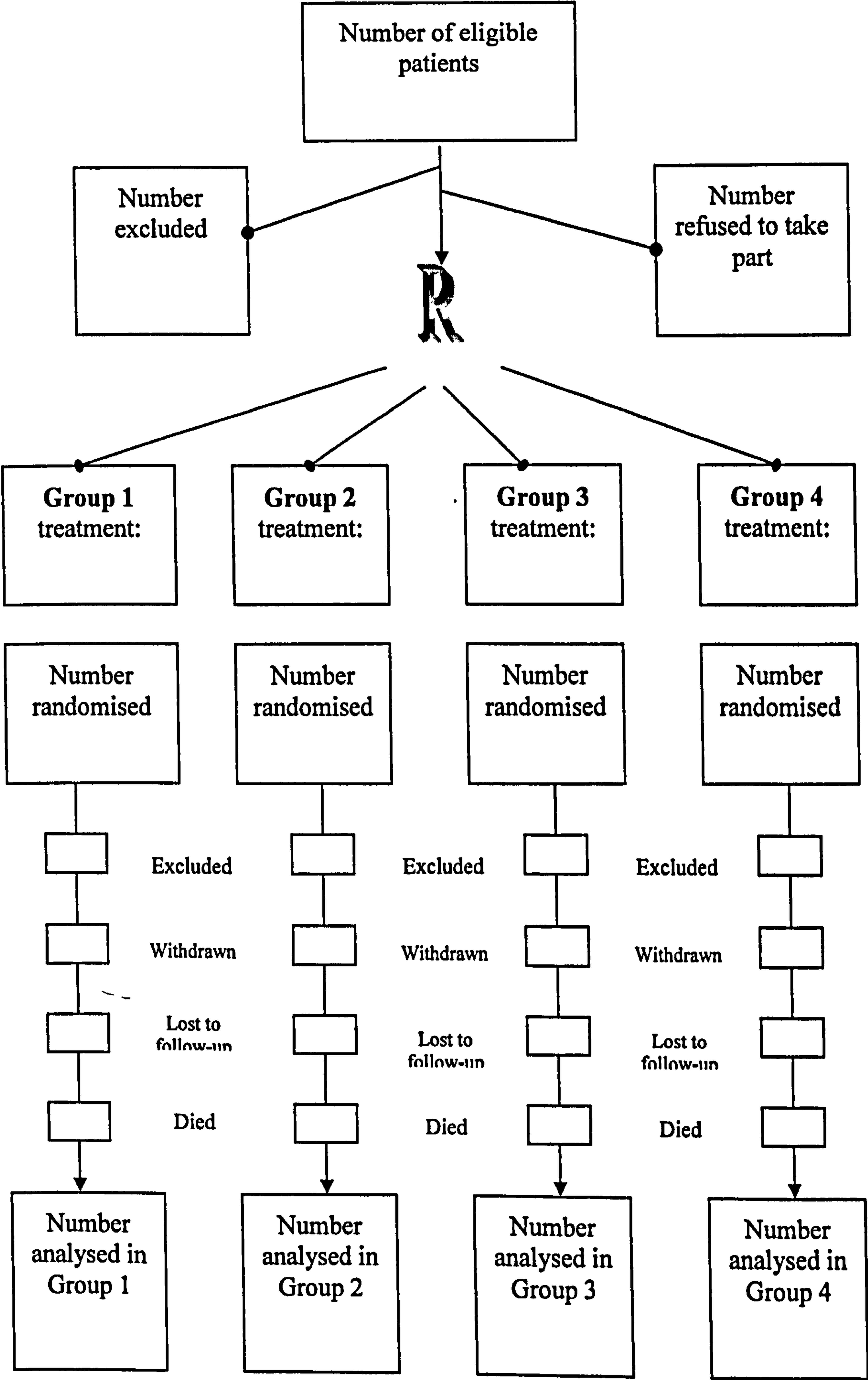
Appendix 2

Data extraction sheets for the systematic review of randomised trials

STUDY PROFILE (Two groups)



STUDY PROFILE (More than two groups)



Study Quality Assessment Form

Grade each of the following aspects of trial quality:

- A – Adequate
- B – Unclear
- C – Inadequate
- D – Not used in this review as a measure of quality

Grade

Selection bias (*allocation concealment*)

1. Was the sequence of allocation of participants to groups concealed until after treatments were allocated?

A: Adequate

- Centralised randomisation either by a central office or pharmacy; On-site computer system, provided that the computer file containing the assignments is locked; Serially numbered sealed opaque envelopes or sequential administration of pre-numbered or coded containers to enrolled participants; Other approaches that appear to offer adequate concealment, combined with the statement that the person who generated the allocation did not administer it.

B: Unclear

- List or table used; Envelopes but no qualifying statement; An apparently adequate concealment but other information in trial indicates concealment may not have been adequate

C: Inadequate

- Alternation; Case record numbers; Dates of birth or days of the week; Any allocation that is entirely transparent before allocation

Performance bias (*masking of participants and researchers*)

2. Were the recipients of care unaware of their assigned treatment?

3. Were persons providing care unaware of the assigned treatment?

Detection bias

4. Were persons assessing outcome unaware of the assigned treatment?

Attrition bias

5. Were rates of follow-up similar in the comparison groups?

6. Was the analysis ‘intention-to-treat’ (were all patients analysed as randomised)?

Study ID: _____

INFORMATION FOR REVMAN INCLUDED STUDIES TABLE

Method	Participants	Interventions	Outcomes	Notes	Allocation concealment
Method of allocation:	Country:	Treatment:	List all relevant outcomes that were collected in the trial:	Any other relevant information:	A Adequate
Masking:	Number randomised:				B Unclear
Participant:					C Inadequate
Provider:	Age:	Control:			D Not used
Outcome:					
Exclusions after randomisation:	Sex:				
Losses to follow-up:	Inclusion criteria:	Duration:			
Unusual study design:	Exclusion criteria:				

Appendix 3

Description of the MRC Trial of the Assessment and Management of Elderly People in the Community

Description of the MRC Trial of the Assessment and Management of Elderly People in the Community

Investigators:

Professor Astrid Fletcher, London School of Hygiene and Tropical Medicine

Dr Dee Jones, University of Wales College of Medicine

Professor Chris Bulpitt, Royal Postgraduate Medical School

Dr Alistair Tulloch, University of Oxford

Collaborator: Professor Mike Drummond (University of York)

Steering Committee:

Professor Andy Haines (Chairman), , Professor Grimley Evans, Professor Karen Luker, Dr Carol Brayne, Professor C Donaldson, Dr M Vickers plus the trial investigators

Observers: Dr Glanz (Department of Health), Dr Henningan (Scottish Health Office)

In 1994 the Medical Research Council funded a large trial to compare different methods of assessment and management of older people: namely targeted versus universal screening, and primary care versus hospital geriatric services. The trial, which is being conducted in 106 General Practices in the UK, will determine the cost effectiveness of these different strategies of assessment and management with effectiveness measured by mortality, hospital admissions and quality of life. The trial is a community-based randomised controlled trial with a 2 stage design. In both stages the unit of randomisation is the general practice.

Stage 1

The aim of Stage 1 is to evaluate the case-finding methods. Practices are equally randomised to a short questionnaire (brief assessment) administered either by post, by a lay person, or by a nurse. Practices are also equally randomised to one of the following: a detailed examination by the study nurse in all patients (irrespective of their

responses on the brief assessment) or a detailed assessment only in those patients who "trigger" on the brief assessment. This design tests targeted (detailed only if triggered) versus universal screening (detailed assessment of all patients). The brief assessment questionnaire, covers all the areas specified in the GP contract with a graded response format to questions on : social environment, activities of daily living, sensory problems (vision and hearing), mobility, physical symptoms including continence, mental condition, use of medication. Additional questions on alcohol consumption, cigarette smoking and physical activity have been included for epidemiological purposes. Criteria for triggering to the detailed assessment are 3 or more problems identified from the brief assessment or any one of 4 "serious" symptoms. The detailed assessment covers the same areas as specified above but in greater depth for example, Glasgow Acuity Charts for vision, whispered voice test for hearing, Mini Mental State Examination for cognitive impairment, and the Geriatric Depression Scale, assessment of symptoms and problems with urinary and faecal continence. Additional biological measurements include: blood pressure, heart rate, anthropometry, dipstix for blood, protein, urine and a blood sample for a full biochemical screen. Patients are also assessed for need for other services such as chiropody, home helps, and home modifications.

Stage 2

The aim of Stage 2 is to evaluate the management of patients identified from the detailed assessment. Practices are equally randomised to the primary care team, or the local multidisciplinary geriatric team, balanced across the Stage 1 randomisation. The study nurse follows a standard protocol based on results and responses in the detailed assessment to make referrals to (i) the teams (ii) other medical services, health care workers or agencies (iii) emergency referrals to the GP. Conditions for referral include common conditions and sources of disability and handicap in older people such as vision and hearing impairment, depression, incontinence.

Outcome measures The principal outcome measures are: mortality and hospital admissions (collected in all practices) and quality of life (collected in a random sample of 23 practices). Trial patients are registered with ONS for mortality follow-up. Use of

services is ascertained by cross sectional and longitudinal sampling throughout the study in order to provide a full economic evaluation.

Trial population The trial is being conducted in practices recruited through the MRC GP Research Framework. Practices are stratified by the key factors that will influence the outcome measures: Jarman score as a measure of deprivation, mortality measured by Standardised Mortality Rates. The patient population included is all patients aged 75 years and over, excluding anyone in long-term care or with terminal disease. 106 practices and over 35,000 patients are participating in the trial with response rates ranging from 80% to the brief questionnaire, 76% to the detailed assessment and 91% to the Quality of life interview. The collection of the baseline assessments is now complete and the trial is in the phase of collecting the outcome data. The trial will terminate data collection at the end of 2000 with publication in 2001.

Appendix 4

Nested vision screening trial procedures manual

**SCREENING OLDER PEOPLE FOR IMPAIRED VISION:
A NESTED TRIAL WITHIN THE MRC TRIAL OF
ASSESSMENT AND MANAGEMENT OF ELDERLY PEOPLE
IN THE COMMUNITY**

Manual of procedures

For further information or if you have any queries

Please contact either Smita Patel or Liam Smeeth at:

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London School of Hygiene and Tropical Medicine
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Introduction	3
Description of study	3
Day to day running of study	5
The assessment schedule	10
Measuring visual acuity	14
Extracting data from patients' notes	20
Making claims	22

INTRODUCTION

This manual of procedures attempts to cover all aspects of the research nurses role in the study. There are bound to be things we have forgotten or that are not clear. Apologies for these: suggestions for improvements are always welcome.

Many of the instructions here will appear to be somewhat basic or simple. We do (honestly) realise that you are experienced nurses who know what you are doing. Many of the things included here are “common sense”. There are good scientific reasons for the simplicity and the lengthy descriptions. These are to ensure that:

- all research nurses follow exactly the same procedures
- you have a reference manual available that will hopefully cover most eventualities.

The main thing is: **please do not feel patronised or insulted.**

DESCRIPTION OF THE VISION SCREENING STUDY

Background

A number of studies have shown that many older people have eyesight problems which are not being treated properly. In 1990, legislation was introduced which required GP's to regularly check the well-being of all their patients over 75 years of age, including eyesight. We recently performed a thorough review of research on vision testing of elderly people in general practice. This showed that merely asking elderly people about their vision did not seem to help. We now need to know whether actually testing older peoples' vision using a chart, and referring people with problems to the eye services, does any good.

As you know, the MRC Elderly Screening Trial was set up a few years ago. It is looking at many different aspects of the well-being of people over 75 years, but without this additional study it cannot tell us whether testing vision actually helps.

How will the new study be carried out?

As part of the MRC Elderly Screening Trial practices were randomly allocated as follows:

- ⇒ Arm A: as one of the 35 questions, participants were asked: “Do you have difficulty seeing newsprint, even if you are wearing glasses.” (*The detailed if positive arm*)
- ⇒ Arm B: as well as the above question in the brief assessment, all participants had a detailed assessment. Distance visual acuity was measured using a Glasgow Acuity Chart and people with reduced vision were referred to an ophthalmologist or advised to see an optician. (*The detailed always arm*)

In this study, we will go back and test the vision of a randomly selected sample of around 150 people. We have randomly selected 10 practices from each of the above two groups.

As well as measuring visual acuity, we want to measure visual function using a specially designed questionnaire. “Visual function” is a measure of the impact of visual problems on a

person's life. In recent years the value of visual function indices in assessing the effectiveness of interventions to improve vision has become widely accepted. We also want to collect data about what happened to those people who were found to have visual problems at the baseline assessment.

By comparing the vision of people in groups A and B, we will be able to find out whether testing older peoples' vision using a chart and referring people with problems to the eye services is effective in improving vision.

How will this study benefit older people?

Visual impairment is a crippling blow to an elderly person and is an important cause of reduced independence, quality of life and of falls. This study has the potential to answer a simple question about how to bring about a real improvement in quality of life to the elderly. The intervention, if effective, is simple and cheap enough to be implemented within the NHS without difficulty.

Who is funding the research?

The study is being funded by the Medical Research Council.

Who is organising the research?

The research is being organised by researchers at the London School of Hygiene and Tropical Medicine and at Moorfields Eye Hospital, London.

The main people involved from the London School of Hygiene and Tropical Medicine are:

- Professor Astrid Fletcher, the principal investigator of the MRC Elderly Screening Trial and the Head of the Epidemiology Unit at the London School of Hygiene and Tropical Medicine.
- Dr Liam Smeeth, a GP and an epidemiologist. He is co-ordinating the study.
- Smita Patel who is responsible for the day to day running of the study.

From Moorfields Eye Hospital:

- Mr Richard Wormald, a consultant ophthalmologist and head of the Ophthalmic Epidemiology Unit
- Jennifer Evans, an ophthalmic epidemiologist.

Richard and Jenny organised the visual component of the baseline assessments in the MRC Elderly Screening Trial.

DAY TO DAY RUNNING OF THE STUDY

Introduction

You will be provided with a list of all patients who need to be invited to have an assessment. The likely total will be around 150.

Your task is to undertake assessments on as many people as possible from this list: ideally all of them. The proportion of people you manage to see is probably the single most important factor in the success of this study.

Who is included?

The list of patients is a random sample drawn from all those patients who were eligible for inclusion in the MRC Elderly Screening Trial. To the best of our knowledge all the patients included in the list were alive and still registered with the practice at the time of putting the lists together (April 2000).

It is very important that as many people as possible are invited to participate. Many people with health problems remain eligible for the study. For example, people in the following groups should *not* be excluded from the study. People who:

- are registered blind or partially sighted
- have recently seen an ophthalmologist or optician
- are on a waiting list for eye treatment, for example cataract surgery
- are housebound
- have hearing impairment
- are infirm or very old
- are depressed
- have cognitive impairment

Who is excluded?

The **only** reasons to exclude people from participating in the study are:

1. The patient has died.
2. The patient has left the practice or moved away.
3. They really are too ill to participate.

By “too ill to participate” we mean that because of illness the patient would find it difficult or unpleasant to complete an assessment, or that you would feel uncomfortable undertaking an assessment. We understand that undertaking assessments with some patients may be difficult or challenging. However, these are likely to be the patients with the most to gain. In addition, it is important for good research practice that as many people as possible are included.

There are two issues to bear in mind in deciding whether someone is too ill to participate. Firstly the assessment is non-invasive. The patient will have nothing physical done to them and only needs to answer some questions and read some letters on a chart. Secondly, many “ill” people are the very people who could gain a lot from help with their eyesight. For example there is good evidence that people who are depressed or housebound tend to have a high level of vision problems, and that they benefit greatly from measures taken to improve their vision.

INVITING PATIENTS TO PARTICIPATE

The invitation letter

Decide a good time for you. If you know that the patient is housebound or virtually housebound, offer to visit them at home.

On the invitation letter:

- fill in the patients name
- delete one of the options “please come to the surgery/ I will visit you at home”
- fill in the time and place

Try and give people between 5 and 10 days notice.

Before the time offered

Telephone the patient a few days before the appointment or suggested visit. Check the following:

- did they receive the invitation?
- could they read it?
- did they understand it?
- Are they happy to participate
- can they attend/ be there when you visit
- do they have any queries or concerns?

If necessary, arrange an alternative time at this point.

What to do if a patient does not arrive or is not in when you visit

We will use the phrase “did not attend” (DNA) for an episode of a patient not arriving at the practice for their appointment or either not being at home or not being ready to have an assessment when you visit.

First “did not attend” (DNA)

If you had not managed to speak to the patient before the appointment, go over the points above. If you had spoken to the patient before the appointment, ask:

- was there a particular problem?
- did they remember the appointment?
- are they still happy to participate?

Arrange another time.

Telephone the patient a few days before the second appointment or suggested visit.

Second DNA

Try and speak to the patient again. Ask:

- was there a particular problem?
- did they remember the appointment?
- are they still happy to participate?

Arrange another time.

If the previous appointments had been at the surgery, offer to come to the patient's home.

Telephone the patient a few days before the third appointment or suggested visit.

Third DNA

Try and speak to the patient again. Use your discretion about whether to try again.

PROBLEMS

The patient is not on the telephone

Most people in this age group will be known to the practice. Find out how the practice normally communicates with the patient.

If necessary, be ready to call round to the patient's home.

The patient finds it difficult to get to the surgery

Please arrange to see them at home.

The patient does not want to come to the surgery or would prefer to be seen at home

You may not feel that a home visit is warranted on health grounds alone. For example you may know the patient does come to the surgery to see the doctor. However, if offering to visit the patient at home means they will have an assessment that they otherwise would not have, then please do arrange to see them at home.

The patient feels they do not need an eye test

This is particularly likely to be true for people who are in one or more of the following groups:

- registered blind or partially sighted
- have recently seen an ophthalmologist or optician
- are on a waiting list for treatment, for example cataract surgery
- housebound

For some patients, such as those who are housebound, this feeling may be due to low expectations in old age or a feeling that nothing can be done to help. They may actually benefit a lot from some help with their eyesight.

For some patients, you may agree with them that they are unlikely to get much benefit from an eye test. We suggest an explanation along the following lines:

“While many older people will benefit from an eye test, it is true that some people may not get a lot of benefit. However, the main reason for testing your eyes at this time is as part of a research study that aims to improve our knowledge of how to help *all* old people with their eyesight. Even if you feel you do not need an eye test or that you will not benefit, by taking part in the study you will be helping other people”.

The patient has died or moved away since the lists of patients were prepared

People may have died or moved away by the time you come to invite them. There are spaces on the patient lists for you to record these details.

THE LOG SHEETS

As well as the list of patients, there are log sheets for you to record everything that happens about each patient in the study. There are two different types of log sheet.

The ‘master’ logsheet

The first version is a master copy that includes details of all the patients. This is for you to keep for the duration of the study. Please fill it in as you go along. Some of the columns ask for a date. Others simply for a tick. There is a column for free text or comments.

For example, if you send out a first invitation letter to a patient, write the date that you sent it in the appropriate box for that patient in the column headed “first invite sent”.

The monthly log sheets

The second version is currently blank apart from the column headings. We would like you to fill in one of these blank log sheets as you go along, using a separate sheet for each month. The monthly log sheets should include details of everything that happens during a single month: from the first day to the last day inclusive. Again, some of the columns ask for a date, others simply for a tick. There is a column for free text or comments.

For example, if you send out a first invitation letter to a patient, fill in the patient’s identification number in the first column and write the date that you sent it in the appropriate box in the column headed “first invite sent”.

Please fill in the month and dates referred to at the top of the sheet. The first sheet should be used from the date you start to the end of the month you start in. For example if you start the study on the 21st of april, you should fill in your first monthly log sheet for the period 21st april to 30th april inclusive. Your second monthly log sheet will be for the period 1st may to 31st may inclusive and so on. Your final log sheet should start on the first day of the final month and end on the day you complete the study.

Once completed, please photocopy the monthly log sheet before returning it to us at the london school of hygiene and tropical medicine.

Returning assessment schedules, consent forms and data extraction forms.

At the end of each month please, preferably within two weeks of the month ending:

1. Check you have completed the master logsheet
2. Check you have completed the relevant monthly logsheet
3. Photocopy the monthly logsheet
4. Check you have all the relevant:
 - Completed assessment schedules
 - Consent forms
 - Data extraction forms for patients who need one.
5. Send us the following by *special delivery*
 - One copy of the monthly logsheet
 - The completed
 - ⇒ Assessment schedules
 - ⇒ Consent forms
 - ⇒ Data extraction forms
6. Start a new monthly log sheet.

Practice staff and administration

You may ask someone in the practice (such as a receptionist or secretary) to do some of the administrative work. This may include tasks such as sending out letters or going to the post office. This is up to you and the practice to decide. If this does happen, please keep a record of how much time they spend on the study. Please use the column on the claim form called “Staff administration costs” (see below).

Screening older people for impaired vision: The assessment schedule

The assessment schedule is in two parts:

1. A questionnaire administered as an interview
2. A test of visual acuity

Questionnaire administration

Role of the interviewer

The interviewer is responsible for:

- ◆ Motivating the patient
- ◆ Asking the patient the questions in the questionnaire in a neutral and standard way
- ◆ Accurately recording the patient's answers

Preparing for the interview

- ◆ Familiarise yourself with the questionnaire. You may find it helpful to practice on a couple of willing volunteers particularly to familiarise yourself with the use of the filter questions in the questionnaire. Hesitation during questionnaire administration can negatively effect rapport with the patient.
- ◆ Look up the required information about the baseline assessment (Q 3.2) and record it in the questionnaire.
- ◆ Flick through the patient's questionnaire beforehand and make sure it has all its pages.
- ◆ Ensure you have a room where you can interview the patient in private and without distraction.
- ◆ Ensure you have somewhere to test visual acuity. This needs to be well-lit with the testing distance of 3 meters already marked out. Use the tape measure provided.
- ◆ Arrange seating appropriately (e.g. if the patient is known to have a hearing problem make sure you are sitting opposite them and they have a clear view of your face. If the patient wears a hearing aid it would be helpful to check they are wearing it and it is turned on).

Using the questionnaire

(a) Dealing with the patient

- ◆ Introduce yourself to the patient. Remind them who you are and why you have asked to see them (please use the attached standard introduction).
- ◆ The questionnaire seeks the *patient's view* on how their vision effects their day-to-day activity and lifestyle. **The interviewer must not influence or guide the patient in their answers.** Ask the questions exactly as they are worded in the questionnaire and record the patient's answer exactly.
- ◆ Be aware of your verbal and non-verbal behaviour. For example, verbal or non-verbal behaviour that conveys surprise, disbelief or sympathy can influence the patient's subsequent answers to questions.
- ◆ It is important that you do not let any prior knowledge of the patient's vision status influence your behaviour to the patient or their responses to the questionnaire.

- ◆ Speak slowly and clearly
- ◆ Give the patient time to think and reply. Adapt the pace of the interview to the patient.
- ◆ Repeat the question if necessary. Do not re-word the question upon repetition.

(b) Visual Function Questionnaire

- ◆ Section 2 of the questionnaire is a standardised Visual Function Questionnaire.
- ◆ Use the folder of flash cards provided.
- ◆ Show the patient the relevant flashcard.
- ◆ Read out the question.
- ◆ Stress the underlined words in your intonation when reading the question to the patient.
- ◆ If necessary repeat the question.
- ◆ Then read out all the possible answers.
- ◆ If the patient states their answer before you have read all the options, ask them to listen to all the possible options first and then answer.

(c) Recording the patient's answers

- ◆ Record the patient's answers during the interview (i.e. do not record the patient's answers from memory).
- ◆ Record the patient's answers clearly and legibly in pen (not pencil). Patient explanations about why they have acted or behaved in a particular way should be recorded as fully as possible.
- ◆ At the end of the interview, before the patient leaves the room, check the questionnaire for completeness. Have all questions been answered?
- ◆ If you tick/circle the wrong answer cross out the mistake and initial the error response. Tick/circle the correct answer.
- ◆ Please do not leave answers blank. It is impossible to know from blank answers whether the question was ever asked. There should always be a way to record "not applicable," or space to write an answer that does not fit into the categories given.
- ◆ Some of the pages in section 3 will only apply to a minority of patients. Please tick the not applicable box at the top of each page that does not apply.

At the end of the assessment, please fill in the section at the bottom of the front cover. In particular decide whether you need to complete a data extraction form.

Troubleshooting

Q What do I do if the patient does not understand a question?

A This should not be a big problem because this is a tried and tested questionnaire. However, if a patient does not understand a question, repeat the question exactly as it is worded in the questionnaire. Do not re-word or interpret the question for the patient. If the patient asks you what a question means ask the patient what they think the question means. If the patient's interpretation is correct then confirm their interpretation as correct. If the patient is not correct ask them what else they think the question might mean, and so guide them to the correct interpretation of the question.

- Q** What do I do if a patient wants to prematurely terminate the interview before finishing the questionnaire?
- A** Ask the patient why they want to stop. If you can shape circumstances to facilitate the completion of the interview please do so. For example, if the patient needs a break for some reason then give them a break. If the patient definitely wants to stop then of course please stop. Remember to record the interview as incomplete on the questionnaire and state the reason why the interview was terminated
- Q** What do I do if I notice an inconsistency in the way the patient has answered the questions (e.g. the patient's answer to a question does not make sense given their answer to a previous question)?
- A** Inconsistencies may occur because the patient misunderstood the question or the interviewer misunderstood the patient's answer or the patient did not express themselves clearly enough. Tell the patient you'd like to check you understood them correctly and would like to repeat the question if that is alright with them. If the patient's response remains 'inconsistent' record their answer and do not question them on their response.
- Q** What do I do if the patient 'jumps the gun' and answers one question with information that will be sought in answer to a later question?
- A** Politely stop the patient and tell them that you'll be asking them about that matter in a minute. Do not jump ahead in the questionnaire and make the related entry. It is important not to alter the sequence of the questionnaire.
- Q** What do I do if I have any other questions about the administration of the questionnaire?
- A** Please contact: Dr Liam Smeeth, Epidemiology Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT Tel: 020 7927 2296 Fax: 020 7580 6897 E mail: liam.smeeth@lshtm.ac.uk

**Screening older people for impaired vision:
standard introduction to the interview assessment**

For the purposes of standardisation it is important that the questionnaire is introduced to all patients in the same way. For that reason please say the following before starting to complete the questionnaire with the patient:

“Hello _____, thank you for taking the time to see me. My name is _____ and I am the nurse who wrote to you. As I mentioned in my letter, we are doing a study to look at the effects of vision screening on older people. This vision study involves answering some questions about what you think about your vision, as well as having your vision checked. The vision check consists of reading some letters on a chart I will show you. The whole thing should take us about 30-45 minutes to complete.

I'd like to repeat that the information from this vision check will be confidential. If I find you have a problem with your vision, then with your permission I will inform your GP. Only myself, your GP and the researchers at the London School of Hygiene & Tropical Medicine will know the identity of people in the study.

Did you get a chance to read the patient information leaflet I sent you with my letter? *(If no, ask if would they like time to read it/ have it read to them now?).*

Have you any questions?

Ask patient to sign consent form

If the patient agrees to proceed:

“Let's start by my asking you a few questions. These questions are about how your vision effects your day-to-day life. The important thing is to tell me what you think about your vision. There are no right or wrong answers to these questions. I will read the questions to you followed by a list of answers that you can choose from. If you'd like me to repeat something or speak more slowly or quickly or loudly just let me know. Here's Question 1..

Screening older people for impaired vision:

Measuring visual acuity

Visual acuity is tested using a Glasgow Acuity Chart. This is actually a booklet and is an example of a special sort of chart called a LogMAR chart. The booklet is a little more complicated than the Snellen charts most people are used to. However there are good reasons for using the Glasgow Acuity Chart rather than the Snellen chart. Design problems in the Snellen chart include the alteration in the number of letters on each line, and the irregular progression of the size of the letters as one moves up or down the chart.

One aspect of the Glasgow Acuity Chart is that a larger score indicates worse vision. Very good vision may produce a minus (negative) score.

Test conditions

Do the test under well-lit conditions but avoid strong overhead lights which may dazzle the patient. Light should shine on the chart but not into the patient's eyes. Keep the lighting conditions constant.

Measure vision at **3 metres**. Use the tape measure provided to measure distance. It is very important that the test is done at 3 metres - considerable effort should be made to find a suitably lit 3 metre space at the practice. For home visits it may not be possible to find a suitable 3 metre space. You may have to do the test at 1 metre. The test is less accurate at 1 metre.

Always tick the box on the form to indicate at which distance the test was done.

Doing the test

Start by testing their vision using both eyes at the same time, followed by each eye separately. When you are testing vision in each eye separately the patient must be asked to cover the other eye. They can use the palm of their hand or the "occluder" part of the pinhole, depending on what is easiest for them. Alternatively a patch may be used.

Glasses

The patient should wear the glasses they normally use for driving or watching television. If they normally do not wear glasses but use them for specific activities requiring distance vision they should put these glasses on for the entire visual acuity test. We want to measure visual deficit arising because patients do not have glasses rather than because they choose not to wear the spectacles which they have been prescribed. The invitation letter asks them to bring any glasses they own with them to the assessment.

Please check any glasses used are reasonably clean: ask the patient to clean them if the lenses are dirty.

Using the booklet

Hold the booklet **vertically**. If it is held at an angle reflections will make the letters difficult to see.

The participant should be encouraged to try and read every letter on a line. Encourage them not to stop if they say they cannot see it: try and get them to attempt every letter. A phrase such as "It doesn't matter if you get it wrong but have a try" may be used to persuade them to finish the line.

If you think the participant may be memorising the letters, you can ask them to read a line from right to left.

The cards

The testing procedure is summarized in the flow chart (page 18).

The first three cards are called the “screener cards.” The remaining cards simply called “line” and a number. The screener cards are used to determine the starting point for the measurement of acuity with the line cards.

Information about each card is printed on the back of the preceding card. This means that the information visible refers to the card that is visible when the booklet is opened flat or opened and folded in two.

The screener cards

Ask the participant to read the letters on screening cards 1 to 3 in turn. The patient should be encouraged to respond until they get a letter wrong. The last successful response to a letter is used to select the appropriate line card to start acuity testing. For example, if a patient reads the four letters on screener card 1 correctly they are shown screener card 2. Now say they read H and O correctly on screener card 2, but then get Y wrong. The smallest letter they read **correctly** was O. The table headed Screener 2 shows you that testing should begin with line card 6 (HYOU).

The line cards

The appropriate card is selected and the patient is asked to try and identify each of the 4 letters presented. If the patient is able to identify correctly 3 or 4 letters on a line then the next card in the series should be presented. If they identify 3 or 4 letters again, go on to the next card. Continue until they can only read 1 or 2 letters correctly on a line. Use the number of letters they identify on this line to score the vision. If they identify 3 or 4 letters and you present the next line but they cannot correctly identify any letters, go back to the previous line and ask them to re-read it. Score this line even if they can still read 3 or 4 letters - you know they cannot read the next line.

The vision is scored according to the number of letters read on the last line on which at least 1 letter can be read. The score should be read off from the score card on the back of the card. For example, if they read 3 letters on line 1 correctly then their score would be 0.825 for a test done at 3 metres.

In the table fill in the line number, number of letters correct and the score.

A larger score indicates worse vision
Good vision may produce a minus (negative) score

Problem: the patient who cannot read any of the letters

If a participant is unable to read Line 1 (the biggest letters) at 3 metres, reduce the test distance to 1 metre (again using the tape measure provided). Take the vision as before, score for "1 metre" in the results table on the back of the testing cards. Tick the 1 metre box on the assessment form. If even at 1 metre they are still unable to read any of Line 1 tick the appropriate box in the questionnaire (unable to read at 1 metre).

The visual acuity results grid

Look up the scores obtained in the grid on page 19 of the assessment schedule. This grid shows all possible measurements with the Glasgow Acuity Card. If any measurement falls in the shaded area (i.e. is 0.5 or greater), it means that the patient has poor vision and should be re-tested with the pinhole.

If all measurements fall in the non-shaded area (i.e. are less than 0.5), that is the end of the test.

Pinhole testing

Before carrying out pinhole testing, write in the scores without pinhole from the previous page for each eye.

Pinhole vision is only done for each eye separately: not for both eyes at the same time. One eye is covered and the patient looks through the pinhole with the other eye. If the patient has problems holding the pinhole they may balance it on their nose - using the "occluder" part to cover the other eye; this is why it is the shape it is.

Take the vision at 3 metres to start with, even if the patient was down to 1 metre distance for initial testing.

In the table fill in the line number, number of letters correct and the score.

If the score in either eye improves with pinhole from 0.5 or more to less than 0.5 then the participant should be advised to see an optician. This means the score fell into the shaded area of the grid without a pinhole but falls into the non-shaded area with the pinhole. When vision improves with a pinhole it indicates that the vision may be improved with glasses.

Anyone whose vision score in either eye remains 0.5 or more using the pinhole (remains in the shaded area) should be referred to an ophthalmologist unless:

- they have been seen by an ophthalmologist in the previous year
- are registered blind or partially sighted

The patient needs to see both an optician and an ophthalmologist

A small number of patients may therefore fit the criteria for being advised to see an optician by the research nurse (because the vision improved in one eye) and be for being referred to an ophthalmologist by the GP (because the vision did not improve in the other eye). This is not a problem. Many patients with eye problems in everyday practice go and see an optician before they see an ophthalmologist.

The vision is worse with the pinhole

Do not be alarmed if vision gets worse with the pinhole - this sometimes happens because the pinhole lets through less light. Use the non-pinhole vision score to decide if the patient needs to be referred to an ophthalmologist: i.e. a score in either eye of 0.5 or more and have not been seen by an ophthalmologist in the previous year and are not registered blind or partially sighted.

Advice about driving

If the patient scored **0.4 or more (e.g. 0.450, 0.575)** when testing both eyes together, their eyesight may be below the currently recommended level of vision required for driving. This means that the logMAR score for both eyes together was *below* the dashed line on the visual acuity results grid.

You will have asked if the patient is currently driving during the interview (Q 15, section 2).

If the patient's vision appears to fall below the driving requirement:

- tell the patient their vision may fall below the level required by law for driving
- advise the patient not to drive until they have had their eyes checked by an optician, their GP or an ophthalmologist
- tell the patient that it is their responsibility not to drive
- tell the patient that you are informing the GP of your findings.
- refer the patient to their GP using the standard notification letter
- advise the patient it may be helpful for them to see an optician for two reasons:

⇒ They will be able to test the patient's eyes more accurately than the test just performed.

⇒ They may be able to improve the patient's vision with new or updated glasses.

It is the patient's responsibility to:

1. Stop driving
2. Inform the Driver and Vehicle Licensing Agency if your findings are confirmed by an optician, ophthalmologist or their GP. The address they should write to is given in the information leaflet.

It is **not** your responsibility to inform the Driver and Vehicle Licensing Agency about your findings.

Give the patient a copy of the study leaflet: INFORMATION FOR DRIVERS

The GP notification letter

Please fill this in for **all** patients. Please tick either “yes” or “no” or “not applicable” (where included). – –

The “snellen equivalent” for the logMAR scores is given on the testing cards. There is a single snellen equivalent for each card, even though each card has four possible logMAR scores. This is because the logMAR scores are more finely detailed.

SUMMARY OF VISUAL ACUITY TESTING

**Use the screening cards to identify
the line at which to start the test**



***Ask the patient to read all 4 letters on the line**

0 letters seen

1 or 2 letters seen

3 or 4 letters seen

**Go back a line
(bigger letters)**

**Score the number
of letters correctly
identified on this
line**

**Go forward a line
(smaller letters)**

**Ask the patient to read
all 4 letters on the line**

**Repeat the
process from***

**Score the number of
letters correctly
identified on this line**

Patient contact with eye services: data extraction forms

The data extraction forms exist to provide a structured way of extracting data about contact with eye services included in the patient's GP record.

A data extraction form should be completed for the following patients:

1. All patients who report ever having seen an ophthalmologist (Q1.4)
2. All patients who were eligible for referral to an ophthalmologist following the baseline assessment of the MRC Elderly Screening Trial (Q3.2b)

The patient does not need to be present for completion of the data extraction form. However, we recommend that you complete the data extraction form soon after seeing the patient.

Please go through the notes and identify ALL the letters which refer to eye problems or deal with referrals to or from any eye specialist - optician, ophthalmologist or eye hospital. Please look through all the notes, not just since the start of the MRC Elderly Study. We are interested in all eye problems, not just those identified during the study.

Please return the completed data extraction form with the completed assessment schedule.

The data extraction form is in two parts.

Section 1

This section relates to the time period prior to the date of the baseline assessment (or the invitation to the baseline assessment for those patients who were eligible for a baseline assessment and did not complete an assessment for any reason).

We do not require complete details of every letter. We need to know:

- whether the patient has ever been referred to anyone about their eyes
- whether the patient has ever seen anyone about their eyes
- what diagnoses were made
- what treatments the patient received.

Fill in the total number of letters which relate to eyes and that are dated prior to the date of the baseline assessment.

Fill in the dates of the earliest and latest letters.

Write down any diagnoses or treatments, with the date (year only).

If you are not sure what a word or some words mean, write them down. If you do not know if something is a diagnosis, treatment or neither of these, write it down where ever there is sufficient space.

You do not need to repeat diagnoses which do not change: write down the earliest reference to it. For example, a patient was diagnosed with chronic open angle glaucoma affecting the left eye and the earliest letter mentioning this diagnosis was dated 1973.

Write down "Chronic open angle glaucoma left eye 1973". You do not need to write down the diagnosis of glaucoma again, even though it will probably be mentioned in subsequent letters.

Not needing to repeat terms only applies to letters dated prior to the date of the baseline assessment.

Section 2

This section relates to the time period on or after the date of the baseline assessment (or the invitation to the baseline assessment for those patients who were eligible for a baseline assessment and did not complete an assessment for any reason).

Please allocate a number to the letters in chronological order, letter number 1 being the first letter identified dated after the date of the baseline assessment. There is a separate space on the form for each letter.

For this section we do require details of every letter relating to eyes or vision. For each letter dated after the baseline assessment please complete the following information:

- who the letter was from and who it was to
- what diagnoses were made
- any treatments that were recommended or the patient received.

Write down any diagnoses or treatments. If you are not sure what a word or some words mean, write them down. If you do not know if something is a diagnosis, treatment or neither of these, write it down where ever there is sufficient space.

If there are more than six letters please use the **extra sheets** provided. Use one extra sheet for each additional letter. On each extra sheet, please fill in:

- the patient identification number
- the letter number as allocated by you.

Please staple the extra sheets to the data extraction form.

**If you have any difficulty with the
Data extraction form please telephone
Liam Smeeth on 020 7927 2297**

MONEY

Making claims

Please send claims **every month** to:

MRC General Practice Research Framework Co-ordinating Centre
MRC Epidemiology and Medical Care Unit
Northwick Park Hospital
Watford Road
Harrow
Middlesex
HA1 3UJ

The study code name is **Smeeth**. This odd choice is to prevent confusion with claims made for the Elderly Screening Trial or for the other vision study that you may have been involved in.

What to claim for

The main items will be:

- Time spent undertaking the assessments
- Time spent travelling to and from home visits
- Travel costs to and from home visits
- Paperwork for each assessment:
 - filling in the GP notification letter
 - completing the data extraction forms when indicated
 - filling in the master and monthly logsheets
- Consumables:
 - telephone calls
 - stationery
 - postage
- Administration:
 - sending out invitations
 - making telephone calls
 - sending completed forms to the London School of Hygiene and Tropical Medicine
 - claims

You may ask someone in the practice (such as a receptionist or secretary) to do some of the administrative work. This is up to you and the practice to decide. If this does happen, please use the “other expenses” section of the claim form

Training

Please claim for:

- your time spent reading over the assessment schedule, data extraction form and procedures manual
- your time spent undergoing training
- any travel expenses.

Appendix 5

Participant invitation letter

Practice headed note paper

Eyesight in older people

Dear _____

We would like to ask for some help with a research study. The study is trying to find out how the Health Service can help improve older people's eyesight. The study is part of a larger study called the MRC Elderly Screening Trial. You may remember having a health check between one and four years ago as part of this larger study.

If you agree to take part, you will have a short interview with the nurse about your eyesight. The nurse will then check your vision by asking you to read some letters on a chart. If you are found to have a problem with your vision, you may be asked to see your GP, be referred to an eye specialist, or the nurse may recommend that you see an optician. The whole appointment will take around 45 minutes to complete.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please read the enclosed information leaflet. Your decision will not affect the standard of care you receive.

Could you please come to the surgery on/ I will visit you at home on:

Please let me know as soon as possible if this time is not convenient for you.

Please bring the following with you when you come:

- ◆ **Your glasses if you have any**
- ◆ **Any letters, appointment cards or other record of when you went to an optician or an ophthalmologist (hospital eye specialist)**

We feel this is a worthwhile study and hope you will be able to take part. I look forward to seeing you.

Yours sincerely,

Appendix 6

Participant information leaflet



Keppel Street, London WC1E 7HT

Direct line: 020 7927 2296

Fax: 020 7580 6897 Email: liam.smeeth@lshtm.ac.uk

**Department of Epidemiology & Population Health
Epidemiology Unit**

Eyesight in older people: information for participants

We are inviting you to take part in a research study. This new study will assist us in looking for the best way to care for elderly people's eyesight. This leaflet will provide information about what the study will involve.

What is the purpose of the study?

The aim of this study is to measure the benefits of different ways of testing for eye problems in older people. It is part of the ongoing Elderly Screening Trial which is funded by the United Kingdom Medical Research Council. We hope this new study will lead to more effective care for those people with problems with their eyesight.

Why have I been chosen?

About 150 patients in your doctor's practice aged 75 and over have been randomly selected to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form when you come and see the nurse. You will be free to withdraw at any time and without giving a reason. Your decision will not affect the standard of care you receive.

What will happen to me if I take part?

You will either need to attend the surgery once or the nurse will come and see you at home. You will be asked to sign a consent form agreeing to take part in the study. You will then have a short interview with the nurse about your eyesight. The nurse will then check your vision by asking you to read some letters on a chart. If you are found to have a problem with your vision, you may be asked to see your GP, be referred to an eye specialist, or the nurse may recommend that you see an optician. The whole appointment will take around 45 minutes to complete.

The nurse will not give you any tablets or medicines, and you will not be asked for a blood sample.

What do I have to do?

Please bring the following with you when you come:

- ◆ Your glasses if you have any
- ◆ Any letters, appointment cards or other record of when you went to an optician or an ophthalmologist (hospital eye specialist)

If the time given is inconvenient, we can offer you a different day or time. You can eat or drink normally before the appointment and you should continue with any medications you are on.

What are the possible disadvantages and risks of taking part?

Apart from spending 30 to 45 minutes with the nurse, there are no disadvantages or risks involved in taking part in this study.

What are the possible benefits of taking part?

A free test of your eyesight! The information we get from this study will inform us about the best way to help older people with their eyesight.

Poor eyesight and driving

If the nurse discovers that your visual acuity (how well you can see) is below the currently recommended level for fitness to drive, she will advise you of this. You will be advised to stop driving immediately. The nurse will advise you to go and see an optician both to confirm her findings and to see if your vision can be improved with new or altered glasses. If the optician confirms the nurse's findings, you will be legally obliged to stop driving and to inform the Driver and Vehicle Licensing Agency of the fact that your vision is below the level required to drive. The nurse will also advise you to see your GP to discuss your fitness to drive.

Will my taking part in this study be kept confidential?

If you consent to take part in the research, the nurse you see as part of the research may inspect your medical records. All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the surgery will have your name and address removed so that you cannot be recognized from it.

What will happen to the results of the research study?

The results will help us carry out future studies about elderly people's eyesight. You will not be able to be identified in any report or publication.

Who is organizing and funding the research?

The study is being organised by researchers at the London School of Hygiene and Tropical Medicine and at Moorfields Eye Hospital, London. The United Kingdom Medical Research Council is funding the study.

Contact for further information

Please contact «Research_Nurse_1» or «Research_Nurse_2», the research nurse at the practice on «Telephone__1»

Appendix 7

Consent form

Name of patient: Date of birth

Patient Identification number:

CONSENT FORM

Title of Project: Eyesight in older people

- 1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
- 3. I give permission for the researchers to have access to my medical records.
- 4. I agree to take part in the above study.

_____ Name of patient	_____ Date	_____ Signature
_____ Name of person taking consent	_____ Date	_____ Signature

Appendix 8

Assessment schedule

Patient ID number

Date of birth

EYESIGHT IN OLDER PEOPLE

ASSESSMENT SCHEDULE

Date of Interview

Interviewer name

.....

Place of Interview

☐ Practice

☐ Patient's home

☐ Other

Before seeing the patient please fill in question 3.2 on page 11

Have the relevant parts of each section been completed?

yes

no

.....

yes

no

.....

yes

no

.....

yes

no

.....

yes

no

.....

N/A

yes

no

.....

N/A

yes

no

.....

yes

no

.....

yes

no

.....

If you answered yes to Q1.4 or Q3.2
please fill in data extraction form

SECTION 1

1.1 Do you have any problems with your eyesight?

☐ Yes ☐ No

1.2 (a) Do you own any glasses?

(If patient is wearing glasses, don't ask, just tick yes)

☐ Yes ☐ No → **If No, go to Question 1.3**

(b) Do you wear them:

- ☐ All the time
- ☐ For reading only
- ☐ Other ***please specify***-----

1.3 Are you registered as blind or partially sighted?

- ☐ No
- ☐ Blind
- ☐ Partially sighted

1.4 Have you ever seen an ophthalmologist/ hospital eye specialist?

- ☐ Yes
- ☐ No

SECTION 2: THE VF-14 QUESTIONNAIRE

2.1

(a)Do you have difficulty, even with glasses, reading small print such as labels
On medicine bottles, a telephone book or food labels?

- ☐ Yes

☐ No

☐ Not Applicable *please give reason* -----

(b)*If yes*, How much difficulty do you currently have?

- ☐ A little

☐ A moderate
amount

☐ A great deal

☐ Unable to do the activity

2.2

(a)Do you have difficulty, even with glasses, reading a newspaper or book?

- ☐ Yes

☐ No

☐ Not Applicable *please give reason* -----

(b)*If yes*, How much difficulty do you currently have?

- ☐ A little

☐ A moderate
amount

☐ A great deal

☐ Unable to do the activity

2.3

(a)Do you have difficulty, even with glasses, reading a large-print book or large print newspaper or numbers on a telephone?

- Yes

No

Not Applicable *please give reason*

(b)*If yes*, How much difficulty do you currently have?

- A little
- A moderate amount
- A great deal
- Unable to do the activity

2.4

(a)Do you have difficulty, even with glasses, recognising people when they are close to you?

- Yes

No

Not Applicable *please give reason*

(b)*If yes*, How much difficulty do you currently have?

- A little
- A moderate amount
- A great deal
- Unable to do the activity

2.5 (a)Do you have difficulty, even with glasses, seeing steps, stairs or kerbs?

- Yes

No

Not Applicable

please give reason

(b)If yes, How much difficulty do you currently have?

- A little
- A moderate amount
- A great deal
- Unable to do the activity

2.6 (a)Do you have difficulty, even with glasses, reading traffic signs, street signs Or shop signs?

- Yes

No

Not Applicable

please give reason

(b)If yes, How much difficulty do you currently have?

- A little
- A moderate amount
- A great deal
- Unable to do the activity

2.7 (a) Do you have difficulty, even with glasses, doing fine handiwork like sewing, knitting, crocheting or carpentry?

-
- ☐ Yes
 - ☐ No
 - ☐ Not Applicable *please give reason*-----

(b) If yes, How much difficulty do you currently have?

- ☐ A little
- ☐ A moderate amount
- ☐ A great deal
- ☐ Unable to do the activity

2.8 (a) Do you have difficulty, even with glasses, writing cheques or filling out forms?

-
- ☐ Yes
 - ☐ No
 - ☐ Not Applicable *please give reason*-----

(b) If yes, How much difficulty do you currently have?

- ☐ A little
- ☐ A moderate amount
- ☐ A great deal
- ☐ Unable to do the activity

2.9

(a) Do you have difficulty, even with glasses, playing games such as bingo, or dominoes?

-
- ☐ Yes

☐ No

☐ Not Applicable *please give reason*

(b) If yes, How much difficulty do you currently have?

- ☐ A little
- ☐ A moderate amount
- ☐ A great deal
- ☐ Unable to do the activity

2.10

(a) Do you have difficulty, even with glasses, taking part in sports like bowling, tennis or golf?

-
- ☐ Yes

☐ No

☐ Not Applicable *please give reason*

(b) If yes, How much difficulty do you currently have?

- ☐ A little
- ☐ A moderate amount
- ☐ A great deal
- ☐ Unable to do the activity

2.11

(a) Do you have difficulty cooking, even with glasses?

-
- ☐ Yes

☐ No

☐ Not Applicable *please give reason*

(b) If yes, How much difficulty do you currently have?

- ☐ A little
- ☐ A moderate amount
- ☐ A great deal
- ☐ Unable to do the activity

2.12

(a) Do you have difficulty, even with glasses, watching television?

-
- ☐ Yes

☐ No

☐ Not Applicable *please give reason*

(b) If yes, How much difficulty do you currently have?

- ☐ A little
- ☐ A moderate amount
- ☐ A great deal
- ☐ Unable to do the activity

2.13

Do you currently drive a car?

☐

Yes (2.13i)

☐

No



If No, go to Question 2.16

2.14

How much difficulty do you have driving during the day because of your Vision? Do you have:-

☐

No difficulty

☐

A little difficulty

☐

A moderate amount of difficulty

☐

A great deal of difficulty

2.15

How much difficulty do you have driving at night because of your Vision? Do you have:-

☐

No difficulty

☐

A little difficulty

☐

A moderate amount of difficulty

☐

A great deal of difficulty

2.16

Have you ever driven a car?

☐ Yes

☐ No → If No, go to Section 3



2.17

When did you stop driving?

- ☐ Less than 6 months ago
- ☐ 6-12 months ago
- ☐ More than 12 months ago

2.18

Why did you stop driving?

- ☐ Vision
- ☐ Other illness
- ☐ Other reason

Any other comments: _____

SECTION 3

3.1 (a) Have you seen anyone about your eyes or bought any glasses in the last five years?

☐ Yes: probably in the last 5 years

☐ No: never or definitely more than 5 years ago

Stop and go to section 4: vision testing

(b) Where was this?

Ask about each of the following options in turn

	Yes	No
Optician	<input type="checkbox"/>	<input type="checkbox"/>
Ophthalmologist (hospital eye specialist)	<input type="checkbox"/>	<input type="checkbox"/>
GP practice	<input type="checkbox"/>	<input type="checkbox"/>
Bought some glasses in a shop or chemist without having an eye test	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>

3.2 Was the patient:

(a) Advised to see an optician after the baseline elderly screening trial assessment?

☐ Yes → go to Question 3.3a

☐ No → Continue from page 13

(b) Referred to an ophthalmologist after the baseline elderly screening trial assessment?

☐ Yes → go to Question 3.3b

☐ No → Continue from page 13

3.3

Do you remember:

(a) being advised to see an optician after the baseline assessment?

or

(b) being referred to an ophthalmologist after the baseline assessment?

☐ Yes

☐ No → **Continue from page 13**

3.4

Did you go to the ophthalmologist / optician as a result of the baseline assessment?

☐ Yes → **Continue from page 13**

☐ No Gently ask why not -----

THIS PAGE IS ONLY FOR THOSE WHO HAVE SEEN AN OPTICIAN:

Tick if not applicable ☐

3.5 What made you decide to go to the optician?

- ☐ Go regularly
- ☐ Problems with eyesight
- ☐ Advised to go by someone Who?
- ☐ Other

3.6 What happened? Were you advised to:

- ☐ Continue with the same glasses
- ☐ Change your lenses or glasses
- ☐ Get some glasses for the first time
- ☐ Other

3.7 If the optician recommended a change in your lenses, or new glasses, did you buy them?

- ☐ Yes ☐ No **Why not**

↓
Continue from page 14 as relevant

3.8 Do you still wear them?

- ☐ Yes ☐ No **Why not**

Continue from page 14 as relevant

Tick if not applicable ☐

3.9

Why did you go to the ophthalmologist?

☐ Referred by GP

☐ Other

3.10

(a) Did they recommend any treatment or help with your eyesight?

☐ Yes

☐ No → **Continue from page 15 as relevant**

(b) What has happened since then?

☐ Nothing Why?

☐ Prescribed some eye medicine, drops or ointment

Name of medicine, drops or ointment if known

☐ On a waiting list for surgery

☐ Had surgery

☐ Referred to another eye service

Details

Please write any further description here:-

.....

**THIS PAGE IS ONLY FOR THOSE WHO HAVE SEEN SOMEONE AT THEIR
GP SURGERY ABOUT THEIR EYES:**

Tick if not applicable ☐

3.11

Why did you go?

3.12

Who did you see?

3.13

What happened during your visit?

THIS PAGE IS ONLY FOR THOSE WHO HAVE SEEN SOMEONE
OTHER THAN AN OPTICIAN, OPHTHALMOLOGIST OR SOMEONE AT THEIR GP
SURGERY ABOUT THEIR EYES:

Tick if not applicable ☐

3.14

Why did you go?

3.15

Who did you see?

3.16

What happened?

SECTION 4: VISUAL ACUITY

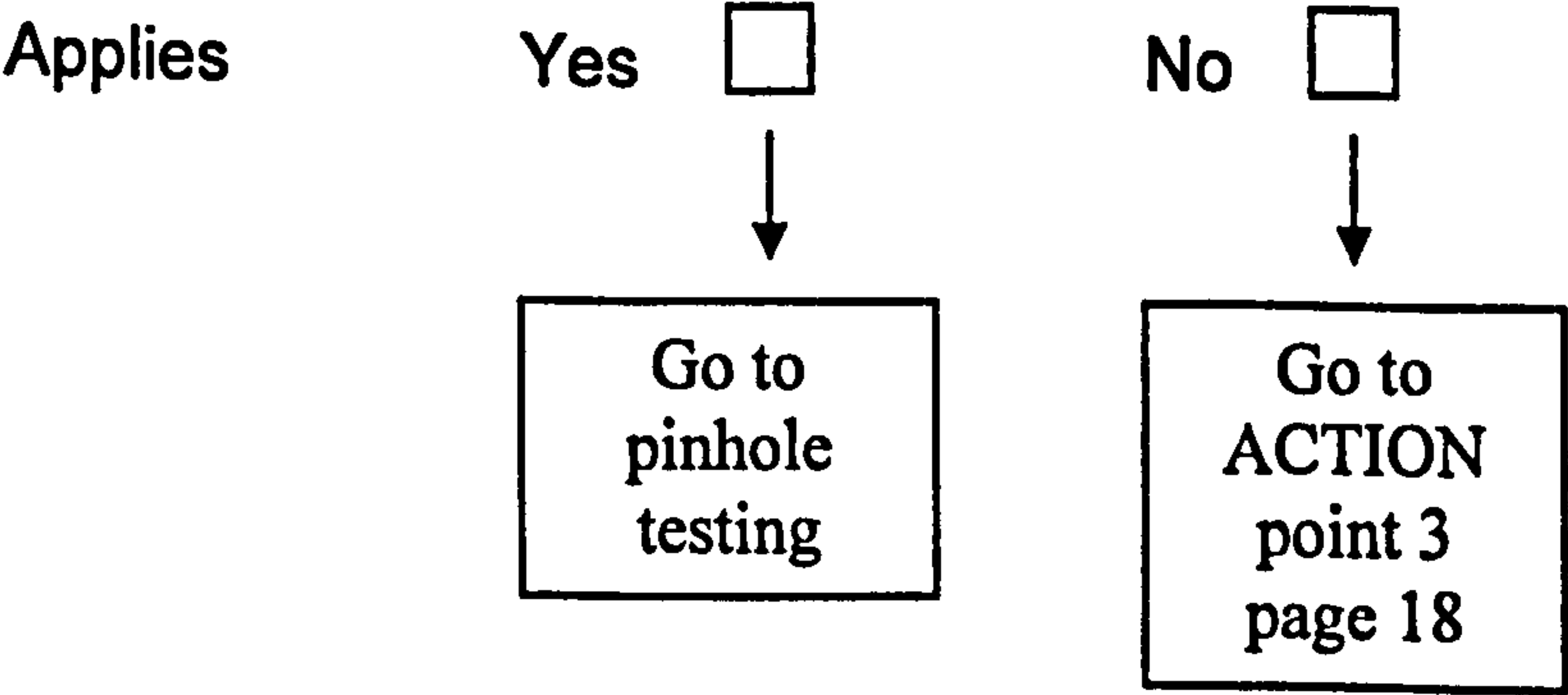
Test the patient whilst they are wearing their usual glasses. Using the Glasgow chart, measure the patient's vision at 3 metres. If the patient cannot see the biggest letters, then measure at 1 metre. Measure both eyes first, then each eye separately. Scores can be plus or minus. The greater the score, the worse the vision.

	Line number	Number correct	Logmar score	Measured at		Unable to read at 1m
				3m	1m	
Both eyes						
Left eye						
Right eye						

Look up the scores obtained in the grid on page 19. This grid shows all possible measurements with the Glasgow Acuity Card. If a measurement falls in the shaded area, it means that the patient has poor vision and should be re-tested with the pinhole. If all measurements fall in the non-shaded area, that is the end of the test.

ACTION

Any shaded (score is 0.5 or greater in either eye): re-test using a pinhole.



PINHOLE TESTING

Tick if not applicable

☐

Before pinhole testing, write in the scores without pinhole for each eye from the previous page.

	Score without pinhole*	With pinhole			Measured at		Unable to read at 1m
		Line number	Number correct	Score			
					3m	1m	
Left eye							
Right eye							

* from previous page

Look up the scores obtained in the grid on page 15. If a measurement that fell in the shaded area without the pinhole falls in the non-shaded area with the pinhole, it suggests that the patient needs new glasses. If the score from either eye is in the shaded area even with the use of the pinhole, this suggests the patient needs to be seen by an ophthalmologist.

ACTION

1. Any score that previously fell in the shaded area without the pinhole falls in the non-shaded area with the pinhole (minus scores, or scores less than 0.5): advise the patient to see an optician.

Patient advised

☐ Yes

☐ No

If No, why not.....

2. Any shaded score even with the pinhole (score is 0.5 or greater in either eye): ask if patient has seen an ophthalmologist/hospital eye specialist in the last year:

☐ Yes

☐ No

If No, recommend GP refers to an ophthalmologist, *unless* the patient is registered as blind or partially sighted (Question 1.3).

Letter sent to GP recommending referral:

☐ Yes

☐ No

If No, why not.....

3. Does the patient currently drive?
(Question 15, section 2)

Yes

☐

Go to point 4

No

☐

End of
acuity
testing

4. If the patient scored **0.4 or more** when testing both eyes together, their eyesight may be below the currently recommended level of vision required for driving. This means that the logMAR score for both eyes together was **below** the dashed line on the visual acuity results grid.

Did the patient score 0.4 or
more when testing both eyes together?

Yes

☐

No

☐

If the answer is yes, their eyesight may be below the currently recommended level of vision required for driving. If the patient is currently driving and their vision appears to fall below the driving requirement, take all the following actions:

Action taken
Yes No

Tell the patient their vision may fall below the level required by law for driving and give them the information leaflet for drivers

☐☐

Advise the patient not to drive until it is clear they can satisfy the medical requirements for fitness to drive (because they have their eyes tested again by an optician, ophthalmologist or their GP and are told their vision is good enough to drive)

☐☐

Tell the patient that it is their responsibility not to drive and to inform the Driver and Vehicle Licensing Agency if the findings are confirmed by an optician, ophthalmologist or their GP.

☐☐

Tell the patient that you are informing their GP of your findings

☐☐

Refer the patient to their GP using the standard notification letter

☐☐

Advise the patient it may be helpful for them to see an optician

☐☐

If any action has been ticked no, please state why.....

Give the patient a copy of the study leaflet: INFORMATION FOR DRIVERS

VISUAL ACUITY RESULTS GRID

GOOD VISION

-0.3	-0.275	-0.25	-0.225
-0.2	-0.175	-0.15	-0.125
-0.1	-0.075	-0.05	-0.025
0	0.025	0.05	0.075
0.1	0.125	0.15	0.175
0.2	0.225	0.25	0.275
0.3	0.325	0.35	0.375
0.4	0.425	0.45	0.475
0.5	0.525	0.55	0.575
0.6	0.625	0.65	0.675
0.7	0.725	0.75	0.775
0.8	0.825	0.85	0.875
0.9	0.925	0.95	0.975
1	1.025	1.05	1.075
1.1	1.125	1.15	1.175
1.2	1.225	1.25	1.275
1.3	1.325	1.35	1.375
Patients who could not read any letters at 1 metre			

BAD VISION

Appendix 9

Example of flashcard used with the National Eye Institute Visual Function Questionnaire

In general, would you say
your overall health is:

Excellent

Very good

Good

Fair

Poor

Appendix 10

Referral letter: research nurse to general practitioner

Screening older people for impaired vision: a nested trial
within the MRC Trial of Assessment and Management
of Elderly People in the community

Notification of results of vision testing

Date:

Re:

Dear

I saw this patient today and tested their vision as part of a vision screening component of the MRC Trial of Assessment and Management of Elderly People in the Community. The results were as follows:

	Logmar score	Snellen equivalent	With use of pinhole	Measured at		Unable to read at 1m
				3m	1m	
Both eyes						
Left eye						
Right eye						

A GP referral to an ophthalmologist
was recommended by the study protocol

Yes ☐ No ☐

(because the patient has visual acuity of less than 6/18 snellen
equivalent that does not improve with use of a pinhole; has not
seen an ophthalmologist for one year or more; and is not
registered blind or partially sighted).

The NHS costs of all such referrals have been approved by the relevant NHS Research and Development
Directorate.

I have advised the patient to see an optician
for formal testing and refractive correction

Yes ☐ No ☐

(because the patient has visual acuity of less than 6/18 snellen
equivalent that improved with use of a pinhole)

Yes ☐ No ☐

Yes ☐ No ☐

Yes ☐ Not applicable ☐

Yes ☐ Not applicable ☐

Research nurse

Dr Liam Smeeth
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Appendix 11

Medical records data extraction form

MRC ELDERLY STUDY: NESTED VISION TRIAL
Patient contacts with hospital eye services

Only for patients eligible for referral to an ophthalmologist following the baseline assessment

ID NUMBER

Date of baseline assessment: ____/____/____

Please go through the notes and identify ALL the letters which refer to eye problems or deal with referrals to or from any eye specialist - optician, ophthalmologist or eye hospital. Please look through all the notes, not just since the start of the MRC Elderly Study. We are interested in all eye problems, not just those identified during the study.

SECTION 1: ANY LETTERS ABOUT EYES DATED BEFORE THE DATE OF THE BASELINE ASSESSMENT

Are there any letters about eyes before the date of the detailed examination yes/no
if no go to section 2

Number of letters:
Ealiest date:
Latest date:

Who are the letters from:
Yes No

GP (referral to eyes services)
Ophthalmologist
Optometrist
Other (details)_____

DIAGNOSIS: Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean.

If you have any difficulty with this form please telephone Liam Smeeth on 020 7927 2296

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean*

[Faint bleed-through from the reverse side of the page]

SECTION 2: ANY LETTERS ABOUT EYES DATED AFTER THE DATE OF THE BASELINE ASSESSMENT

Are there any letters about eyes after the date of the baseline assessment yes/no

if no stop

Number of letters:

Ealiest date:

Latest date:

GP REFERRAL

Is there a referral letter to an ophthalmologist dated after the date of the baseline assessment yes/no

If no, is there any other evidence of a referral eg a note in the medical record yes/no

Details

Date of referral

RESPONSE FROM OPHTHALMOLOGIST

Are there any letters from an ophthalmologist dated after the date of the baseline assessment

If the patient was referred, is there a letter that states the patient did not attend the appointment yes/no

Date of letter

ALL LETTERS ABOUT EYES DATED AFTER THE DATE OF THE BASELINE ASSESSMENT

If you have any difficulty with this form please telephone Liam Smeeth on 020 7927 2296

Please allocate a number to the letters in chronological order, letter number 1 being the first letter identified dated after the date of the baseline assessment. If there are more than 6 letters please use extra sheets being sure to fill in the id number for each. For each letter dated after the baseline assessment please complete the following information:

LETTER NUMBER 1

Date of letter ____ / ____ / ____

PURPOSE OF LETTER: *eg, report from ophthalmologist, referral to optician*

DIAGNOSIS: *Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean. Please record any vision measurements.*

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean*

LETTER NUMBER 2

Date of letter ____ / ____ / ____

PURPOSE OF LETTER: *eg, report from ophthalmologist, referral to optician*

If you have any difficulty with this form please telephone Liam Smeeth on 020 7927 2296

DIAGNOSIS: *Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean. Please record any vision measurements.*

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean.*

LETTER NUMBER 3	Date of letter ____ / ____ / ____
------------------------	--

PURPOSE OF LETTER: *eg, report from ophthalmologist, referral to optician*

DIAGNOSIS: *Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean. Please record any vision measurements.*

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean*

LETTER NUMBER 4	Date of letter ____ / ____ / ____
-----------------	-----------------------------------

PURPOSE OF LETTER: *eg, report from ophthalmologist, referral to optician*

DIAGNOSIS: *Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean. Please record any vision measurements.*

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean*

LETTER NUMBER 5	Date of letter ____ / ____ / ____
-----------------	-----------------------------------

PURPOSE OF LETTER: *eg, report from ophthalmologist, referral to optician*

DIAGNOSIS: *Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean. Please record any vision measurements.*

If you have any difficulty with this form please telephone Liam Smeeth on 020 7927 2296

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean*

LETTER NUMBER 6

Date of letter ____ / ____ / ____

PURPOSE OF LETTER: *eg, report from ophthalmologist, referral to optician*

DIAGNOSIS: *Please write down any terms which you think refer to the diagnosis even if you are not sure what they mean. **Please record any vision measurements.***

TREATMENT: *Please write down any terms which you think refer to treatment even if you are not sure what they mean*

Any other comments:

Appendix 12

The relationship between Snellen visual acuity and logMAR scores

The relationship between Snellen visual acuity and logMAR scores

Snellen acuity at 6 metres	logMAR score
6/3	-0.3
6/3.75	-0.2
6/5	-0.1
6/6	0.0
6/7.5	0.1
6/9.5	0.2
6/12	0.3
6/15	0.4
6/19	0.5
6/24	0.6
6/30	0.7
6/38	0.8

Notes:

- The logMAR score is derived from the angular size of the smallest letters that can be read. Larger angles indicate worse vision, and therefore higher logMAR scores indicate lower visual acuity.
- Because a logMAR score of 0.0 is to equate to a Snellen acuity of 6/6, logMAR acuity better than 6/6 will have a negative sign.
- Each line on the logMAR chart has four letters, and each letter correctly identified reduces the logMAR score by 0.025 log units. Thus identifying all four letters on a line reduces the logMAR score by 0.1 units, and the next smallest line is then tested.

